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ICON PLC /ADR/
Form 20-F
August 30, 2004

FORM 20-F

(Mark One)

/ / REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE
SECURITIES EXCHANGE ACT OF 1934

OR

/X/ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934

For the fiscal period ended: May 31, 2004

OR

/ / TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934.

Commission file number:

ICON public limited company

.....

(Exact name of Registrant as specified in its charter)

Ireland

.....

(Jurisdiction of incorporation or organization)

South County Business Park, Leopardstown, Dublin 18, Ireland.

.....

(Address of principal executive offices)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

| | |
|---------------------|---|
| Title of each class | Name of exchange on which registered |
|---------------------|---|

None

Securities registered or to be registered pursuant to Section 12(g) of the Act:

Title of each class

American Depository Shares, representing Ordinary Shares, par value (euro)0.06
each Ordinary Shares, par value (euro)0.06 each

Securities for which there is a reporting obligation pursuant to Section 15(d)
of the Act:

None

(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of
capital or common stock as of the close of the period covered by the annual
report: 13,838,476 Ordinary Shares.

Indicate by check mark whether the registrant (1) has filed all reports required
to be filed by Section 13 or 15(d) of the Securities Exchange Act 1934 during
the preceding 12 months (or for such shorter period that the registrant was
required to file such reports), and (2) has been subject to such filing
requirements for the past 90 days:

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Yes.....X.....

No.....

Indicate by check mark which financial statement item the registrant has elected to follow:

Item 17.....

Item 18.....X.....

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General

As used herein, "ICON plc" and the "Company" refer to ICON public limited company and its consolidated subsidiaries, unless the context requires otherwise.

Unless otherwise indicated, ICON's financial statements and other financial data contained in this Form 20-F are presented in United States dollars ("\$") and are prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP").

In this Form 20-F, references to "U.S. dollars," "U.S.\$" or "\$" are to the lawful currency of the United States, references to "pounds sterling", "sterling", "(pound)", "pence" or "p" are to the lawful currency of the United Kingdom, references to "Israeli Shekels" or "ILS" are to the lawful currency of Israel, references to "Euro" or "(euro)" are to the European single currency adopted by twelve members of the European Union (including the Republic of Ireland, France, Germany & the Netherlands). ICON publishes its consolidated financial statements in U.S. dollars.

ICON prepares its consolidated financial statements on the basis of a fiscal year beginning on June 1 and ending on May 31. References to a fiscal year in this Form 20-F shall be references to the fiscal year ending on May 31 of that year. In this Form 20-F, financial results and operating statistics are, unless otherwise indicated, stated on the basis of such fiscal years.

Cautionary Statement

Statements included herein which are not historical facts are forward looking statements. Such forward looking statements are made pursuant to the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995 (the "PSLRA"). The forward looking statements involve a number of risks and uncertainties and are subject to change at any time. In the event such risks or uncertainties materialize, our results could be materially affected. The risks and uncertainties include, but are not limited to, dependence on the pharmaceutical industry and certain clients, the need to regularly win projects and then to execute them efficiently, the challenges presented by rapid growth, competition and the continuing consolidation of the industry, the dependence on certain key executives and other factors identified in ICON's Securities and Exchange Commission filings. ICON has no obligation under the PSLRA to update any forward looking statements and does not intend to do so.

Part I

Item 1. Identity of Directors, Senior Management and Advisors.

Not applicable.

Item 2. Offer Statistics and Expected Timetable.

Not applicable.

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Item 3. Key Information.

Selected Historical Consolidated Financial Data for ICON plc

The following selected financial data set forth below are derived from ICON's consolidated financial statements and should be read in conjunction with, and are qualified by reference to, "Operating and Financial Review and Prospects" and ICON's consolidated financial statements and related notes thereto included elsewhere in this Form 20-F.

| | 2000 | 2001 | Year Ended M 2002 | |
|---|------------|------------|----------------------|-----|
| (in thousands, except share and per | | | | |
| ----- | | | | |
| Statement of Operations Data: | | | | |
| Gross revenue | \$115,087 | \$151,832 | \$218,842 | \$ |
| Subcontractor costs (1) | (34,320) | (35,669) | (62,287) | (1 |
| ----- | | | | |
| Net revenue | 80,767 | 116,163 | 156,555 | |
| Costs and expenses: | | | | |
| Direct costs | 42,007 | 63,800 | 83,371 | |
| Selling, general and administrative | 27,348 | 36,312 | 48,951 | |
| Merger costs (3) | 1,617 | - | - | |
| Depreciation and amortization | 3,264 | 4,975 | 6,020 | |
| ----- | | | | |
| Total costs and expenses | 74,236 | 105,087 | 138,342 | |
| ----- | | | | |
| Income from operations | 6,531 | 11,076 | 18,213 | |
| Net interest income | 2,659 | 2,519 | 1,116 | |
| ----- | | | | |
| Income before provision for income taxes | 9,190 | 13,595 | 19,329 | |
| Provision for income taxes | (3,122) | (2,617) | (5,129) | |
| ----- | | | | |
| Net income (4) | \$6,068 | \$10,978 | \$14,200 | |
| ----- | | | | |
| Net income per ordinary share (2) (4): | | | | |
| Basic | \$0.55 | \$0.97 | \$1.22 | |
| ----- | | | | |
| Diluted | \$0.51 | \$0.92 | \$1.16 | |
| ----- | | | | |
| Weighted average number of ordinary shares outstanding: | | | | |
| Basic | 11,050,556 | 11,292,610 | 11,656,153 | 11, |
| ----- | | | | |
| Diluted | 11,824,359 | 11,943,849 | 12,241,820 | 12, |
| ----- | | | | |
| Pro forma information | | | | |
| Adjustment for pro forma income taxes (3) | 537 | | | |
| ----- | | | | |

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| | |
|--------------------------------|--------|
| Pro forma net income | 6,605 |
| ----- | |
| Net income per ordinary share: | |
| Basic | \$0.60 |
| ----- | |
| Diluted | \$0.56 |
| ----- | |

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| | As of May 31, | | | |
|---------------------------|----------------|-----------|-----------|-----------|
| | 2000 | 2001 | 2002 | 2003 |
| | ---- | ---- | ---- | ---- |
| | (in thousands) | | | |
| Balance Sheet Data: | | | | |
| Cash and cash equivalents | \$ 26,552 | \$ 11,179 | \$ 36,291 | \$ 18,311 |
| Short term investments | 21,405 | 35,941 | 18,551 | - |
| Working capital | 57,962 | 61,147 | 72,923 | 53,827 |
| Total assets | 100,118 | 128,967 | 165,794 | 235,014 |
| Total debt | 2,251 | 11,518 | 11,745 | 7,126 |
| Government grants | 533 | 476 | 962 | 1,140 |
| Shareholders' equity | \$77,053 | \$86,580 | \$107,561 | \$136,910 |

- (1) Subcontractor costs comprise investigator payments and certain other costs reimbursed by clients under terms specific to each of ICON's contracts. See Note 2(d) to the consolidated financial statements.
- (2) Net income per ordinary share is based on the weighted average number of outstanding ordinary shares and in the case of diluted net income per share includes potential ordinary shares from the exercise of options.
- (3) On January 28, 2000, ICON completed a merger with Pacific Research Associates Inc. ("PRAI"), a company specializing in data management, statistical analysis, and medical and regulatory consulting based in Mountain View, USA. The merger with PRAI was accounted for as a pooling-of-interests transaction and accordingly, the historical financial information contained within this Form 20-F reflects the combined results of ICON and PRAI.

The adjustment for pro forma income taxes is to normalize the tax charge in relation to PRAI. As PRAI was treated as an S-Corporation (with no corporate tax therefore charged to income) prior to the merger with ICON.

- (4) As explained in Note 17 to our Audited Consolidated Financial Statements, ICON adopted Statement of Financial Accounting Standards

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("SFAS") No.142 effective June 1, 2001. Under SFAS No.142, goodwill and intangible assets with indefinite lives are no longer amortized, but instead are tested for impairment at least annually. The following table provides a reconciliation of reported net income to adjusted net income and earnings per ordinary share excluding amortization expense for all periods presented:

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| | 2000 | 2001 | Year ended May 31 2002 (in thousands) |
|---|---------|----------|---|
| Reported net income | \$6,068 | \$10,978 | \$14,200 |
| Add back goodwill amortization | 38 | 210 | - |
| ----- | ----- | ----- | ----- |
| Adjusted net income | \$6,106 | \$11,188 | \$14,200 |
| ----- | ----- | ----- | ----- |
| | | | (in dollars) |
| Basic net income per ordinary share reported | \$0.55 | \$0.97 | \$1.22 |
| Add back goodwill amortization | - | \$0.02 | - |
| ----- | ----- | ----- | ----- |
| Adjusted basic net income per ordinary share reported | \$0.55 | \$0.99 | \$1.22 |
| ----- | ----- | ----- | ----- |
| | | | (in dollars) |
| Diluted net income per ordinary share reported | \$0.51 | \$0.92 | \$1.16 |
| Add back goodwill amortization | - | \$0.02 | - |
| ----- | ----- | ----- | ----- |
| Adjusted diluted net income per ordinary share reported | \$0.51 | \$0.94 | \$1.16 |
| ----- | ----- | ----- | ----- |

Risk Factors

You should carefully consider the following factors and any other information in this document before deciding to purchase our American Depository Shares ("ADSs").

We are dependent on the continued outsourcing of research and development by the pharmaceutical, biotechnology and medical device industries.

We are dependent upon the ability and willingness of the pharmaceutical, biotechnology and medical device companies to continue to spend on research and development and to outsource the services that we provide. We are therefore subject to risks, uncertainties and trends that affect companies in these industries. We have benefited to date from the tendency of pharmaceutical, biotechnology and medical device companies to outsource clinical research

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projects. Any downturn in these industries or reduction in spending or outsourcing could adversely affect our business. For example, if these companies expanded upon their in-house clinical or development capabilities, they would be less likely to utilize our services. In addition, if governmental regulations were changed, they could affect the ability of our clients to operate profitably, which may lead to a decrease in research spending and therefore this could have a material adverse effect on our business.

We depend on a limited number of clients and a loss of or significant decrease in business from them could affect our business.

We have in the past and may in the future derive a significant portion of our net revenue from a relatively limited number of clients. During the fiscal year ended May 31, 2004, 40% of our net revenue was derived from our top five clients. In fiscal 2004, 17% of our net revenue was from Astra Zeneca, no other client contributed more than 10% of net revenues. During the fiscal year ended May 31, 2003, 51% of our net revenue was derived from our top five clients. In fiscal 2003, 21% of our net revenue was from Astra Zeneca, 11% from Sanofi-synthelabo inc. and 10% from Pfizer. During the fiscal year ended May 31, 2002, 60% of our net revenue was derived from our top five clients. In fiscal 2002, 16% of our net revenue was from Astra Zeneca, 14% from Pfizer and 12% from Bristol Myers Squibb. The loss of, or a significant decrease in business from, one or more of these clients could have a material adverse effect on our business.

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If our clients discontinue using our services, or cancel or discontinue projects, our revenue will be adversely affected and we may not receive their business in the future or may not be able to attract new clients.

Our clients may discontinue using our services completely or cancel some projects either without notice or upon short notice. The termination or delay of a large contract or of multiple contracts could have a material adverse effect on our revenue and profitability. Historically, clients have canceled or discontinued projects and may in the future cancel their contracts with us for reasons including:

- o the failure of products being tested to satisfy safety or efficacy requirements;
- o unexpected or undesired clinical results of the product;
- o a decision that a particular study is no longer necessary;
- o insufficient patient enrollment or investigator recruitment; or
- o production problems resulting in shortages of the drug.

If we lose clients, we may not be able to attract new ones, and if we lose individual projects, we may not be able to replace them.

We compete against many companies and research institutions that may be larger or more efficient than we are. This may preclude us from being given the opportunity to bid, or may prevent us from being able to competitively bid on and win new contracts.

The market for CROs is highly competitive. We primarily compete against in-house departments of pharmaceutical companies and other CROs including Quintiles Transnational Corporation, Covance Inc., PAREXEL International Corp.,

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Kendle International Inc., Ingenix Inc. (United Health), Omnicare Inc., PRA Inc., MDS Inc., Inveresk Research Group, Inc. and Pharmaceutical Product Development, Inc. Some of these competitors have substantially greater capital, research and development capabilities and human resources than we do. As a result, they may be selected as preferred vendors of our clients or potential clients for all projects or for significant projects, or they may be able to price projects more competitively than us.

Any of these factors may prevent us from getting the opportunity to bid on new projects or prevent us from being competitive in bidding on new contracts.

Our quarterly results are dependent upon a number of factors and can fluctuate from quarter to quarter.

Our results of operations in any quarter can fluctuate depending upon, among other things, the number and scope of ongoing client projects, the commencement, postponement, variation and termination of projects in the quarter, the mix of revenue, cost overruns, employee hiring and other factors. Our net revenue in any period is directly related to the number of employees and the percentage of these employees who were working on projects and billed to the client during that period. We may be unable to compensate for periods of underutilization during one part of a fiscal period by augmenting revenues during another part of that period. We believe that operating results for any particular quarter are not necessarily a meaningful indication of future results.

Approximately 80% of our net revenue is earned from long-term fixed-fee contracts. We would lose money in performing these contracts if the costs of performance exceed the fixed fees for these projects.

Approximately 80% of our net revenue is earned from long-term fixed-fee contracts. We have in the past and therefore will continue to bear the risk of cost overruns under these contracts. If the costs of performing these projects exceed the fixed fees for these projects, for example if we underprice these contracts, if there are significant cost overruns or if there are unanticipated delays under these contracts, our business, financial condition and operating results could be adversely affected.

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If we fail to attract or retain qualified staff, our performance may suffer.

Our business, future success and ability to expand operations depends upon our ability to attract, hire, train and retain qualified professional, scientific and technical operating staff. We compete for qualified professionals with other CROs, temporary staffing agencies and the in-house departments of pharmaceutical, biotechnology and medical device companies. Although we have not had any difficulty attracting or retaining qualified staff in the past, there is no guarantee that we will be able to continue to attract a sufficient number of clinical research professionals at an acceptable cost.

Failure to comply with the regulations of the U.S. Food and Drug Administration and other regulatory authorities could result in substantial penalties and/or loss of business.

The U.S. Food and Drug Administration, or FDA, and other regulatory authorities inspect us from time to time to ensure that we comply with their

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regulations and guidelines, including environmental and health and safety matters. In addition, we must comply with the applicable regulatory requirements governing the conduct of clinical trials in all countries in which we operate. If we fail to comply with any of these requirements we could suffer:

- o the termination of any research;
- o the disqualification of data;
- o the denial of the right to conduct business;
- o criminal penalties; and
- o other enforcement actions.

Our exposure to exchange rate fluctuations could adversely affect our results of operations.

We derived approximately 37.6% of our consolidated net revenue in 2004 from our operations outside of the United States. Our financial statements are presented in U.S. dollars. Accordingly, changes in exchange rates between the U.S. dollar and other currencies in which we report local results, including the pound sterling and the euro, will affect the translation of a subsidiary's financial results into U.S. dollars for purposes of reporting our consolidated financial results.

In addition, our contracts with our clients are sometimes denominated in currencies other than the currency in which we incur expenses related to such contracts. Where expenses are incurred in currencies other than those in which contracts are priced, fluctuations in the relative value of those currencies could have a material adverse effect on our results of operations. We regularly review our currency exchange exposure and hedge a portion of this exposure using forward exchange contracts.

Liability claims brought against us could result in payment of substantial damages to plaintiffs and decrease our profitability.

We contract with physicians who serve as investigators in conducting clinical trials to test new drugs on their patients. This testing creates the risk of liability for personal injury to or death of the patients. Although investigators are generally required by law to maintain their own liability insurance, we could be named in lawsuits and incur expenses arising from any professional malpractice actions against the investigators with whom we contract. To date, we have not been subject to any liability claims that are expected to have a material effect on us.

Indemnifications provided by our clients against the risk of liability for personal injury to or death of the patients vary from client to client and from trial to trial and may not be sufficient in scope or amount or the providers may not have the financial ability to fulfill their indemnification obligations. Furthermore, we would be liable for our own negligence.

In addition, we maintain an appropriate level of worldwide Professional Liability/Error and Omissions Insurance. The amount of coverage we maintain depends upon the nature of the trial. We may in the future be unable to maintain or continue our current insurance coverage on the same or similar terms. If we are liable for a claim that is beyond the level of insurance coverage, we may be responsible for paying all or part of any award.

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Item 4. Information on the Company.

General

We are a contract research organization, or CRO, providing clinical research and development services on a global basis to the pharmaceutical, biotechnology and medical device industries. Our focus is on supporting the conduct of clinical trials. We have historically done so by providing such services as Phase I - IV clinical trials management, study design, laboratory services and drug development support. We believe that we are one of a select group of CROs with the capability and expertise to conduct clinical trials in most major therapeutic areas on a global basis. As of May 31, 2004, we had approximately 2,450 employees and operations in 33 locations in 20 countries, including the United States and major markets in Europe and Rest of World and have managed clinical trials in over 50 countries. For the fiscal year ended May 31, 2004, we derived approximately 62.4%, 34.0% and 3.6% of our net revenue in the United States, Europe and Rest of World, respectively.

Headquartered in Dublin, Ireland, we began operations in 1990 and have expanded our business through internal growth and strategic acquisitions.

During the fiscal year ended May 31, 2004, we commenced operations in Budapest, Hungary, Barcelona, Spain, and Hong Kong, China.

On July 3, 2003, we entered into a creditline facility for a total of U.S.\$60 million. This facility was entered into jointly with Bank of Ireland plc and Ulster Bank Ireland Ltd, and replaced existing Allied Irish Banks plc and PNC facilities.

On August 6, 2003, we completed a secondary offering on the NASDAQ exchange raising approximately \$44.3 million, after the deduction of costs, through the issuance of an additional 1.5 million shares at \$32.25 per share.

On September 9, 2003, we completed the acquisition of Globomax LLC, a leading US drug development company which provides a range of development and consulting services to the pharmaceutical, biotechnology industries and medical device.

On July 1, 2004 we acquired 70% of the outstanding share capital of Beacon Bioscience, Inc., a leading specialist CRO, which provides a range of medical imaging services to the pharmaceutical, biotechnology and medical device industries.

ICON plc's principal executive office is located at: South County Business Park, Leopardstown, Dublin 18, Republic of Ireland. The contact telephone number of this office is 353 (1) 291 2000.

Industry Overview

The CRO industry provides independent product development services for the pharmaceutical, biotechnology and medical device industries. Companies in these industries outsource product development services to CROs in order to manage the drug development process more efficiently and cost-effectively to maximize the profit potential of patent-protected products. The CRO industry has evolved since the 1970s from a small number of companies that provided limited clinical services to a larger number of CROs that offer a range of services that encompass the entire research and development process, including pre-clinical development, clinical trials management, clinical data management, study design, biostatistical analysis, central laboratory and regulatory affairs services. CROs are required to provide these services in accordance with good clinical and laboratory practices, as governed by the applicable regulatory authorities.

The CRO industry is highly fragmented, consisting of several hundred small, limited-service providers and a limited number of medium-sized and large CROs with global operations. Although there are few barriers to entry for small, limited-service providers, we believe there are significant barriers to becoming a CRO with global capabilities. Some of these barriers include the infrastructure and experience necessary to serve the global demands of clients, the ability to manage simultaneously complex clinical trials in numerous countries, broad therapeutic expertise and the development and maintenance of the complex information technology systems required to integrate these capabilities. In recent years, the CRO industry has experienced consolidation, resulting in the emergence of a select group of CROs that have the capital, technical resources, integrated global capabilities and expertise to conduct multiple phases of clinical trials on behalf of pharmaceutical, biotechnology and medical device companies. We believe that some large pharmaceutical companies, rather than utilizing many CRO service providers, are selecting a limited number of CROs who are invited to bid for projects. We believe that this trend will further concentrate the market share among CROs with a track record of quality, speed, flexibility, responsiveness, global capabilities and overall development experience and expertise.

Trends Affecting the CRO Industry

CROs derive substantially all of their revenue from the research and development expenditures of pharmaceutical, biotechnology and medical device companies. Based on industry surveys and investment analyst research, we estimate that clinical development expenditures outsourced by pharmaceutical and biotechnology companies worldwide in 2003 was in excess of \$14 billion. We believe that the following trends create further growth opportunities for global CROs, although there is no assurance that growth will materialize.

Increasing Drug Development Activity.

Recent improvements in drug discovery and screening technology, biotechnology and disease pathology have reduced the time to develop new drug candidates. These improvements, combined with the threat of patent expirations on existing drugs, have led drug developers to increase the rate at which they are creating new drug candidates for clinical trials. As the number of trials that need to be performed increases, we believe that drug developers will increasingly rely on CROs to manage these trials in order to continue to focus on drug discovery. In addition, as many biotechnology companies do not have a clinical development infrastructure, we believe that the services offered by CROs will continue to be in demand from such companies.

Pressure to Accelerate Time to Markets; Globalization of the Marketplace.

Reducing product development time maximizes the client's potential period of patent exclusivity, which in turn maximizes potential economic returns. We believe that clients are increasingly using CROs that have the appropriate expertise to improve the speed of product development to assist them in improving economic returns. In addition, applying for regulatory approval in multiple markets and for multiple indications simultaneously, rather than sequentially, reduces product development time and thereby maximizes economic returns. We believe that CROs with global operations and experience in a broad range of therapeutic areas are a key resource to support a global regulatory approval strategy.

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Cost Containment Pressures.

Over the last several years, drug companies have sought more efficient ways of conducting business due to margin pressures stemming from patent expirations, greater acceptance of generic drugs, pricing pressures caused by the impact of managed care, purchasing alliances and regulatory consideration of the economic benefit of new drugs. Consequently, drug companies are centralizing research and development, streamlining their internal structures and outsourcing certain functions to CROs, thereby converting previously fixed costs to variable costs. The CRO industry, by specializing in clinical trials management, is often able to perform the needed services with greater focus and at a lower cost than the client could perform internally.

Increasing Number of Large Long-Term Post-Marketing Studies.

We believe that to establish competitive claims and to encourage drug prescription by physicians in some large and competitive categories, more clients need to conduct outcome studies to demonstrate, for example, that mortality rates are

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reduced by certain drugs. To verify such outcomes, very large patient numbers are required and they must be monitored over long time periods. We believe that as these types of studies increase there will be a commensurate increase in demand for the services of CROs who have the ability to quickly assemble large patient populations, globally if necessary, and manage this complex process throughout its duration.

Increasing Regulatory Demands.

We believe that regulatory agencies are becoming more demanding with regard to the data required to support new drug approvals and are seeking more evidence that new drugs are safer and more effective than existing products. As a result, the complexity of clinical trials and the size of regulatory submissions are driving the demand for services provided by CROs.

Company Operating Procedures

We have developed a unique operating model for clinical trial projects based on a "dedicated team approach" in which a team of full time professionals, operating out of centralized offices, is assigned exclusively to each project. This contrasts with the approach of many competitors whose staff typically work on multiple projects at once, sometimes operating from non-office bases in remote locations and some of whom may be part-time. We believe that this operating model offers the following advantages:

- o each client's project receives undivided attention and is executed efficiently as team members do not have conflicting demands;
- o the absence of conflicting demands on the project team also ensures a high quality service;
- o the dedicated team approach allows us to develop strong relationships with our clients and to be more responsive to our clients' needs;
- o focused project teams facilitate efficient supervision of the project, enhance productivity and improve cost control; and

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- o less administration is required to co-ordinate assignments, leading to a more streamlined corporate management structure.

We believe our dedicated team approach has led to repeat business and an expanding client base.

Strategy

We believe that our operating model based on dedicated teams differentiates us from our competition in the CRO industry and enables us to deliver high quality services to our clients. Our strategy is to continue to grow by applying this model to penetrate further our existing client base and add new clients. We intend to implement our strategy by continuing to deliver high quality services, by increasing our geographic presence and by expanding the scale and range of our services. We intend to supplement our internal growth with strategic acquisitions.

Continue to Deliver High Quality Services and Customer Satisfaction. We believe that our dedicated team approach allows us to provide high quality, timely and cost effective services that are designed to be highly responsive to our clients' needs. We believe that the resulting customer satisfaction and enhanced reputation in the industry will continue to enable us to penetrate our existing client base and add new clients. In the fiscal year ended May 31, 2004, approximately 97% of our net revenue was derived from second or subsequent projects with clients.

Expand Geographic Presence. We believe that the capability to provide our services on a global basis in most major and developing pharmaceutical markets enhances our ability to compete for new business from large multinational pharmaceutical, biotechnology and medical device companies. We have expanded geographically through the establishment of 33 offices in 20 countries and intend to continue expanding into regions that have the potential to increase our client base or increase our investigator and patient populations.

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Increase Scale and Range of Services. We seek to enhance our competitive position by increasing the scale and range of our services. We intend to expand our clinical trials, central laboratory, IVRS (interactive voice recognition system), data management, statistical and consulting operations in order to capitalize further on the outsourcing opportunities currently available from our clients.

Services

Consistent high quality performance is what we have come to stand for with our clients, and a large part of our continued success is due to the high quality standards we have set and delivered on projects to date. The achievement of these quality goals is made possible by the implementation and maintenance of an effective quality management system, which not only ensures that our business and quality objectives are achieved, but which is sufficiently dynamic to rapidly respond to changes in the clinical research and regulatory environments.

We maintain an integrated quality management system, which is designed to serve the business needs while complying with Good Corporate Practice ("GCP") guidelines, and which is structured according to the requirements of ISO 9000 international standards. The quality management documentation includes over 700 standard operating procedures ("SOP"s), working procedures and policies that are implemented on a global basis. In addition, our independent quality assurance

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division has the responsibility for assuring that processes conform to pre-determined quality, ethical and regulatory standards.

One of the driving forces behind our quality performance is management commitment to ISO 9000. Since 1994 when we were first registered to ISO 9002, we have continued to undergo several quality systems surveillance audits each year, in order to maintain global registration. In 2003 we attained the new ISO 9001:2000 standard.

This global registration is unique in the industry and demonstrates our commitment to providing exceptional clinical research management services. We remain the only CRO to have ISO registration across all offices and functions.

During fiscal 2004, our Phase I unit achieved ISO 9001:2000 registration and more new offices are scheduled to undergo the registration audits in 2005. These include offices in South Africa and Canada. Further improvements are resulting in a more effective internal auditing strategy, which combines the advantages and efficiency of operational risk assessment, with a process-focused approach on tasks that are critical to quality and customer satisfaction.

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The range of clinical research services we provide facilitates the collection, analysis and reporting of clinical trials data, which will ultimately become part of a client's drug registration submission. The range of services is outlined below:

Clinical Pharmacology

A critical step in the clinical development process is the confirmation of safety and efficiency in new drug candidates. This is achieved through the execution of Clinical Pharmacology or Phase I studies. These studies are undertaken to determine the metabolic and pharmacological effects of drug candidates in healthy volunteers.

Bioanalysis

Supporting the clinical development process, bioanalysis is carried to source the data required for pharmacokinetic and pharmacodynamic analysis. Bioanalysis quantifies the drug and its major metabolites in samples collected from cell culture media, plasma, serum, and urine.

Pharmacokinetic and Pharmacodynamic analysis

Pharmacokinetic analysis is carried out to measure the effects of absorption, distribution and elimination of a drug and its metabolites. Pharmacodynamic analysis assesses the effects of new drug candidate on the physiology of the body

Study Protocol Preparation

This study protocol is the critical document provided to the investigator which defines the study and details the procedures which must be followed for the proper conduct of the trial. ICON has extensive experience in preparing study protocols in a broad range of therapeutic areas.

Case Report Form ("CRF") Preparation

The CRF is a study specific document in which the investigator records all

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relevant information on a trial patient in accordance with the requirements of the protocol. ICON has the capability of producing CRFs for a wide variety of therapeutic indications and in all required languages.

Clinical Trial Approvals

Prior to start-up, all clinical trials must be approved by the relevant government agencies, by institutional review boards and ethics committees and by certain other bodies in accordance with local requirements. ICON has extensive experience in obtaining such approvals on a multinational basis.

Investigator Recruitment

The success of a clinical trial is dependent upon finding experienced investigators who are capable of performing clinical trials in accordance with the highest ethical and scientific standards. We have a database of several thousand such investigators who are experienced in numerous therapeutic areas and who have successfully completed many clinical trials for us.

Study Monitoring and Data Collection

As patients in a clinical trial are examined and tests are conducted in accordance with the study protocol, patient data is recorded on CRFs and laboratory reports. In order to ensure accurate results, we provide:

- . Specially trained monitors who visit sites regularly to ensure that the CRFs are completed correctly and that all data specified in the protocol are collected.
- . Personnel who review CRFs for consistency and accuracy before the data is entered into an electronic database.
- . Study monitoring and data collection services which comply with the FDA's good clinical practice guide lines and other relevant regulatory requirements.

Patient Safety Monitoring

In a clinical trial, patient safety is paramount. We have teams of trained physicians and paramedical staff who review any serious adverse events which may occur during a trial and prepare detailed reports of these events on a timely basis for the pharmaceutical company and regulatory bodies as required.

Clinical Data Management

As the study progresses, the data from the CRFs is entered into databases that are designed in accordance with the specifications of the project and the particular needs of the client. We provide:

- . Personnel who screen the data to detect errors, omissions or other deficiencies prior to data entry.
- . Study specific computer programs which are written in order to validate the data.
- . The creation of a final database that is electronically transferred to a biostatistical group for subsequent analysis.

Biostatistical Services

Our biostatistical group primarily provides detailed analyses of data generated

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from clinical trials. In addition to providing this in-house statistical support, our biostatisticians assist clients with all phases of drug development through biostatistical consulting, database design, data analysis and statistical reporting.

Medical Reporting

The results of the statistical analysis of the data collected during the trial, together with other clinical data are included in a final clinical trial report, which may then become part of the drug registration submission. ICON's medical reporting team prepare this report and may assist in the presentation of the data in different formats, including for journal publication or for presentation to international symposia.

Central Laboratory Services

An important element in monitoring patient safety during a clinical trial is the conduct of various laboratory tests on the patient's blood, urine and other bodily fluids at appropriate intervals during the trial. The analysis of these samples must be standardized and the results must be promptly transmitted to the investigator. Our central laboratory operation provides:

- . A broad range of sample analyses.
- . An efficient logistics system to ensure rapid receipt of samples from the investigator. . State of the art analytical technology.
- . Electronic transmission of test results to the investigator.

IVR (Interactive Voice Response)

IVR systems use the global telecommunication networks to transfer data to a single, centrally located database. IVR systems are used in clinical studies primarily for study site administration, enrolling and randomizing patients, management of clinical supplies and collection of patient diaries.

Animal Health

The Animal Health division of ICON has broad capabilities in clinical research for the development of drugs, vaccines, and devices for the global animal health industry. The combination of expertise and geographical reach puts ICON in the top tier of animal CROs globally. This group has been dedicated to animal health clinical research for over 10 years and has experience in all target species and all major pharmacological classes. Capabilities include: Complete clinical project management, contract monitoring, data management, statistical analysis, quality assurance services, final study reports, development consulting and post-marketing survey management.

Regulatory Consultancy

Medicinal products are subject to strict regulatory requirements throughout their development, testing and marketing. Authorization by drug regulatory authorities is necessary prior to any product being marketed. The regulatory processes and requirements are lengthy and complex. ICON's regulatory consultancy division provides consultancy on global regulatory requirements during development, advises on suitability of client's documentation for regulatory approvals, prepares and submits applications for regulatory approvals and provides post licensing regulatory support services.

Strategic Drug Development Services

The Strategic Development division of ICON has broad expertise and can offer a full range of global services including regulatory affairs, CMC strategy and management, product development strategy, project management through all phases of

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clinical development, product life cycle management, quality, compliance, pharmacokinetics, biopharmaceutics, biostatistics, clinical research, preclinical research, data management, programming and biostatistics.

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Organizational Structure

| Name | Country of incorporation | Gro |
|---------------------------------------|--------------------------|-----|
| ICON Clinical Research (UK) Limited | United Kingdom | |
| ICON Clinical Research Inc. | USA | |
| ICON Clinical Research Limited | Republic of Ireland | |
| ICON Japan K.K. | Japan | |
| ICON Clinical Research GmbH | Germany | |
| ICON Clinical Research Pty Limited | Australia | |
| ICON Clinical Research S.A. | Argentina | |
| ICON Clinical Research SARL | France | |
| ICON Clinical Research Pte. | Singapore | |
| ICON Clinical Research Israel Limited | Israel | |
| Medeval Group Limited | UK | |
| ICON Laboratories, Inc. | USA | |
| Managed Clinical Solutions, Inc. | USA | |
| ICON Clinical Research (Canada) Inc. | Canada | |
| Globomax LLC | USA | |
| ICON Clinical Research Espana S.L. | Spain | |
| ICON Clinical Research Kft | Hungary | |

All shareholdings comprise ordinary shares.

All subsidiary undertakings are involved in the provision of contract research services to the pharmaceutical, biotechnology and medical device industries.

Information Systems

Our information technology strategy is to build systems that help in the delivery of our business strategy. The focus is to provide ease of access to information for our staff and clients. Our current information systems are built around open standards and leading commercial hardware and software. All critical business systems are formally delivered following a documented approach. Critical clinical information systems which manage clinical data are validated in accordance with the latest FDA regulations.

Recognizing that each client has its own requirements and systems, we seek to ensure an entirely flexible approach to client needs. An example of this flexibility includes linking directly to client systems or for a client to have access to designated ICON systems. Frequently, we have established secure wide area network, or WAN, links to the client's data systems, have trained our staff in those systems and have delivered data on-line to the client's database. We also provide secure remote access to our systems for clients to review their study information.

We have deployed a suite of software applications that assist in the management of our activities. These software applications are both internally developed and commercially available applications from leading vendors in the industry. These include a clinical trials management application that tracks all relevant data in a trial and automates all management and reporting processes and an investigator grants management application which utilizes this tracking data to trigger payments when they become due to investigators. We have also developed an interactive voice response system to increase the efficiency of clinical trials. This system provides features such as centralized patient randomization, drug inventory management, and patient diary collection and provides our clients with a fully flexible data retrieval solution which can be utilized via telephone, internet browser or WAP enabled device.

In our central laboratory, we utilize a comprehensive suite of software, including a laboratory information management system (LIMS), a kit/sample management system and a web interface system to allow clients to review results online.

Our IT systems are operated from two centralised hubs in Philadelphia and Dublin. Other offices are linked to these hubs through a resilient network that is both internally managed and outsourced to a leading telecommunications provider. Travelling staff can also access all systems via secure remote dial up facilities. A global corporate Intranet portal provides access to all authorized data and applications for our internal staff.

Sales and Marketing

Our global sales and marketing strategy is to focus our business development efforts on pharmaceutical, biotechnology and medical device companies whose development projects are advancing. By developing and maintaining close relationships with our clients, we gain repeat business and achieve lateral penetration into other therapeutic divisions where applicable. Simultaneously, we are actively establishing new client relationships.

While our sales and marketing activities are carried out locally by executives in each of our major locations, the sales and marketing process is coordinated centrally. In addition, all of our business development professionals, senior

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executives and project team leaders share responsibility for the maintenance of key client relationships and business development activities.

Clients

In 2004 revenue was earned from over 350 clients, including all of the top 30 pharmaceutical companies as ranked by 2003 revenues.

We have expanded geographically in order to pursue larger multi-national clinical trials in markets worldwide and have expanded through acquisition to offer a broader range of services. In the fiscal year ended May 31, 2004, 62.4% of our net revenue was generated in the United States, 34.0% in Europe and 3.6% in Rest of World.

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We have in the past and may in the future derive a significant portion of our net revenue from a relatively limited number of major projects or clients. During the fiscal year ended May 31, 2002, we received 16% of our net revenue from Astra Zeneca, 14% from Pfizer and 12% from Bristol Myers Squibb. In fiscal year 2003, we received 21% of our net revenue from Astra Zeneca, 11% from Sanofi-Synthelabo Inc. and 10% from Pfizer. In fiscal year 2004, we received 17% of our net revenue from Astra Zeneca. No other client contributed more than 10% of net revenues in fiscal 2004. We believe that the importance of certain clients reflects our success in penetrating our client base. The loss of, or a significant decrease in business from one or more of these key clients could result in a material adverse effect.

Contractual Arrangements

We are generally awarded contracts based upon our response to requests for proposals received from pharmaceutical, biotechnology and medical device industries.

Most of our revenues are earned from contracts which are fixed price, based on certain activity and performance specifications. Consequently, although we typically bear the cost of overruns, with certain exceptions, we benefit if our costs are lower than anticipated. Payment terms usually provide either for payments based on the achievement of certain identified milestones or activity levels or monthly payments according to a fixed payment schedule over the life of the contract. Where clients request changes in the scope of a trial or in the services to be provided by us, we deal with these by a change order, often resulting in additional revenue to us. We also contract on a "fee-for-service," "days worked" or "time and materials" basis but this accounts for approximately 20% of revenues.

Contract terms may range from one year to several years depending on the nature of the work to be performed. In most cases, a portion of the contract fee, typically 10% to 20%, is paid at the time the study or trial is started. The balance of the contract fee payable is generally payable in installments over the study or trial duration and may be based on the achievement of certain performance targets or "milestones" or, to a lesser extent, on a fixed monthly payment schedule. For instance, installment payments may be based on patient enrollment or delivery of the database. Reimbursable expenses are typically estimated and budgeted within the contract and invoiced on a monthly basis. Reimbursable expenses include payments to investigators, travel and accommodation costs and various other direct costs incurred in the course of the clinical trial which are fully reimbursable by the client.

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Most of our contracts are terminable immediately by the client with cause in certain circumstances and on 30-60 days notice without cause. In the event of termination, we are entitled to all sums owed for work performed through the notice of termination and certain costs associated with termination of the study. Some of our contracts provide for an early termination fee. Termination or delay in the performance of a contract occurs for various reasons, including, but not limited to, unexpected or undesired results, production problems resulting in shortages of the drug, adverse patient reactions to the drug, the client's decision to de-emphasize a particular trial or inadequate patient enrollment or investigator recruitment.

Backlog

Our backlog consists of potential net revenue yet to be earned from projects awarded by clients

At May 31, 2004, we had a backlog of \$464 million, compared with approximately \$352 million at May 31, 2003. We believe that our backlog as of any date is not necessarily a meaningful predictor of future results, due to the potential for cancellation or delay of the projects underlying the backlog, and no assurances can be given that we will be able to realize this backlog as net revenue.

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Competition

The CRO industry is highly fragmented, consisting of several hundred small, limited-service providers and a limited number of medium-sized and large CROs with global operations. We primarily compete against in-house departments of pharmaceutical companies and other CROs with global operations. Some of these competitors have substantially greater capital, technical and other resources than us. CROs generally compete on the basis of previous experience, the quality of contract research, the ability to organize and manage large-scale trials on a global basis, the ability to manage large and complex medical databases, the ability to provide statistical and regulatory services, the ability to recruit suitable investigators, the ability to integrate information technology with systems to improve the efficiency of contract research, an international presence with strategically located facilities, financial viability, medical and scientific expertise in specific therapeutic areas and price. We believe that we compete favorably in these areas. Our principal CRO competitors are Quintiles Transnational Corporation, Covance Inc., PAREXEL International Corp., Kendle International Inc., Ingenix Inc. (United Health), Omnicare, Inc., PRA Inc., MDS Inc, Inveresk Research Group, Inc. and Pharmaceutical Product Development, Inc. The trend toward CRO industry consolidation has resulted in heightened competition among the larger CROs for clients and acquisition candidates.

Government Regulation

Regulation of Clinical Trials

The clinical investigation of new drugs is highly regulated by government agencies. The standard for the conduct of clinical research and development studies is good clinical practice, which stipulates procedures designed to ensure the quality and integrity of data obtained from clinical testing and to protect the rights and safety of clinical subjects. While good clinical practice has not been formally adopted by the FDA or, with certain exceptions, by similar

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regulatory authorities in other countries, some provisions of good clinical practice have been included in regulations adopted by the FDA. Furthermore, in practice, the FDA and many other regulatory authorities require that study results submitted to such authorities be based on studies conducted in accordance with good clinical practice.

Regulatory authorities, including the FDA, have promulgated regulations and guidelines that pertain to applications to initiate trials of products, the approval and conduct of studies, report and record retention, informed consent, applications for the approval of drugs and post-marketing requirements. Pursuant to these regulations and guidelines, service providers that assume the obligations of a drug sponsor are required to comply with applicable regulations and are subject to regulatory action for failure to comply with such regulations and guidelines. In the United States and Europe, the trend has been in the direction of increased regulation by the applicable regulatory authority. We believe that many pharmaceutical companies do not have the resources to comply with all of these regulations and standards and that this has contributed and will continue to contribute to the growth of third-party service providers.

In providing our services in the United States, we are obligated to comply with FDA requirements governing such activities. These include obtaining patient informed consents, verifying qualifications of investigators, reporting patients' adverse reactions to drugs and maintaining thorough and accurate records. We must maintain source documents for each study for specified periods, and such documents may be reviewed by the study sponsor and the FDA during audits.

The services we provide outside the United States are ultimately subject to similar regulation by the relevant regulatory authority, including the Medicines Control Agency in the United Kingdom and the Bundesinstitut für Arzneimittel und Medizinprodukte in Germany. In addition, our activities in Europe are affected by the Committee for Proprietary Medicinal Products of the European Union, and its successor, the European Medicines Evaluation Agency, which is based in London, England.

We must also retain records for each study for specified periods for inspection by the client and by the applicable regulatory authority during audits. If such audits document that we have failed to comply adequately with applicable regulations and guidelines, it could result in a material adverse effect. In addition, our failure to comply with applicable regulation and guidelines, depending on the extent of the failure, could result in fines, debarment, termination or suspension of ongoing research or the disqualification of data, any of which could also result in a material adverse effect.

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New Drug Development - An Overview

Before a new drug may be marketed, the drug must undergo extensive testing and regulatory review in order to determine that the drug is safe and effective. The following discussion primarily relates to the FDA approval process. Similar procedures must be followed for clinical trials in other countries. The stages of this development process are as follows:

Preclinical Research (1 to 3.5 years). "In vitro" (test tube) and animal studies are conducted to establish the relative toxicity of the drug over a wide range of doses and to detect any potential to cause birth defects or cancer. If results warrant continuing development of the drug, the manufacturer will file for an Investigational New Drug Application, or IND, upon which the FDA may grant permission to begin human trials.

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Clinical Trials (3.5 to 6 years)

Phase I (6 months to 1 year). Basic safety and pharmacology testing in 20 to 80 human subjects, usually healthy volunteers, includes studies to determine how the drug works, if it is safe, how it is affected by other drugs, where it goes in the body, how long it remains active and how it is broken down and eliminated from the body.

Phase II (1 to 2 years). Basic efficacy (effectiveness) and dose-range testing in 100 to 200 patients to help determine the best effective dose, confirm that the drug works as expected, and provide additional safety data.

Phase III (2 to 3 years). Efficacy and safety studies in hundreds or thousands of patients at many investigational sites (hospitals and clinics). These studies can be placebo-controlled trials, in which the new drug is compared with a "sugar pill", or studies comparing the new drug with one or more drugs with established safety and efficacy profiles in the same therapeutic category.

TIND (May span late Phase II, Phase III, and FDA review). When results from Phase II or Phase III show special promise in the treatment of a serious condition for which existing therapeutic options are limited or of minimal value, the FDA may allow the manufacturer to make the new drug available to a larger number of patients through the regulated mechanism of a Treatment Investigational New Drug, or TIND. Although less scientifically rigorous than a controlled clinical trial, a TIND may enroll and collect a substantial amount of data from tens of thousands of patients.

NDA Preparation and Submission. Upon completion of Phase III trials, the manufacturer assembles the statistically analyzed data from all phases of development into a single large submission, the New Drug Application, or NDA, which today comprises, on average, approximately 100,000 pages.

FDA Review & Approval (1 to 1.5 years). Data from all phases of development (including a TIND) is scrutinized to confirm that the manufacturer has complied with regulations and that the drug is safe and effective for the specific use (or "indication") under study.

Post-Marketing Surveillance and Phase IV Studies. Federal regulation requires the manufacturer to collect and periodically report to the FDA additional safety and efficacy data on the drug for as long as the manufacturer markets the drug (post-marketing surveillance). If the drug is marketed outside the U.S., these reports must include data from all countries in which the drug is sold. Additional studies (Phase IV) may be undertaken after initial approval to find new uses for the drug, to test new dosage formulations, or to confirm selected non-clinical benefits, e.g., increased cost-effectiveness or improved quality of life.

Potential Liability and Insurance

We contract with physicians who serve as investigators in conducting clinical trials to test new drugs on their patients. Such testing creates a risk of liability for personal injury to or death of the patients resulting from adverse reactions to the drugs administered. In addition, although we do not believe we are legally accountable for the medical care rendered by third party investigators, it is possible that we could be subject to claims and expenses arising from any professional malpractice of the investigators with whom we contract. We also could be held liable for errors or omissions in connection with the services we perform.

We believe that the risk of liability to patients in clinical trials is mitigated by various regulatory requirements, including the role of institutional review boards and the need to obtain each patient's informed consent. The FDA requires each human clinical trial to be reviewed and approved by the institutional review board at each study site. An institutional review board is an independent committee that includes both medical and non-medical personnel and is obligated to protect the interests of patients enrolled in the trial. After the trial begins, the institutional review board monitors the protocol and measures designed to protect patients, such as the requirement to obtain informed consent.

We further attempt to reduce our risks through contractual indemnification provisions with clients and through insurance maintained by clients, investigators and us. However, the contractual indemnifications generally do not protect us against certain of our own actions such as negligence, the terms and scope of such indemnification vary from client to client and from trial to trial, and the financial performance of these indemnities is not secured. Therefore, we bear the risk that the indemnity may not be sufficient or that the indemnifying party may not have the financial ability to fulfill its indemnification obligations. We maintain worldwide professional liability insurance. We believe that our insurance coverage is adequate. There can be no assurance, however, that we will be able to maintain such insurance coverage on terms acceptable to us, if at all. We could be materially adversely affected if we were required to pay damages or bear the costs of defending any claim outside the scope of or in excess of a contractual indemnification provision or beyond the level of insurance coverage or in the event that an indemnifying party does not fulfill its indemnification obligations.

Description of Property

We lease all but one of our facilities under operating leases.

Our principal executive offices are located in South County Business Park, Leopardstown, Dublin, Republic of Ireland, where we own an office facility of approximately 42,000 square feet on approximately two acres which includes an extension completed in August 1999. We have also leased an additional office facility of approximately 25,000 square feet in the same business park.

We also maintain U.S. offices in Chicago, Philadelphia, Nashville, Irvine, San Francisco, Houston, Wilmington, Raleigh, Baltimore, Tampa and two offices in New York. Our European subsidiaries maintain offices in Southampton, Frankfurt, Paris, Moscow, Amsterdam, Marlow, Manchester, Tel Aviv, Stockholm, Riga, Budapest and Barcelona. Our Rest of World offices are located in Tokyo, Singapore, Sydney, Bangalore, Buenos Aires, Johannesburg, Montreal, and Hong Kong.

Item 5. Operating and Financial Review and Prospects.

The following discussion and analysis should be read in conjunction with our Consolidated Financial Statements, accompanying notes and other financial information, appearing in Item 18. The Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States.

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Overview

ICON plc is a contract research organization, providing clinical research and development services on a global basis to the pharmaceutical, biotechnology and medical device industries. We specialize in the management, execution and analysis of complex multi-national clinical trials. Headquartered in Dublin, Ireland, we began operations in 1990 and, to date, have expanded our business through internal growth and strategic bolt-on acquisitions. As of May 31, 2004, we had approximately 2,450 employees and operations in 33 locations in 20 countries, including the United States and major markets in Europe and Rest of World. In fiscal 2004, 62.4%, 36.0% and 3.6% of our net revenue was derived in the United States, Europe and Rest of World, respectively. See Note 15 to the Consolidated Financial Statements.

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Revenue consists primarily of fees earned under contracts with third-party clients. In most cases, a portion of the contract fee is paid at the time the study or trial is started, often upon the signing of a letter of intent, and the balance of the contract fee is generally payable in installments over the study or trial duration, based on the achievement of certain performance targets or "milestones." Revenue for contracts is recognized on the basis of the relationship between time incurred and the total estimated duration of the trial or on a fee-for service basis according to the particular circumstances of the contract. As is customary in the CRO industry, we subcontract with third party investigators in connection with clinical trials. All subcontractor costs, and certain other costs where reimbursed by clients, are, in accordance with industry practice, deducted from gross revenue to arrive at net revenue. As these costs vary from contract to contract, we view net revenue as our primary measure of revenue growth.

Direct costs consist primarily of compensation and associated fringe benefits for project-related employees and other direct project driven costs. Selling, general and administrative expenses consist of compensation and related fringe benefits for selling and administrative employees, professional services, advertising costs and all costs related to facilities and information systems.

Our backlog consists of potential net revenue yet to be earned from projects awarded by clients. At May 31, 2004, we had a backlog of \$464 million, compared with approximately \$352 million at May 31, 2003. We believe that our backlog as of any date is not necessarily a meaningful predictor of future results, due to the potential for cancellation or delay of the projects underlying the backlog, and no assurances can be given that we will be able to realize this backlog as net revenue.

As the nature of ICON's business involves the management of projects having a typical duration of one to three years, the commencement or completion of projects in a fiscal year can have a material impact on revenues earned with the relevant clients in such years. In addition, as we typically work with some, but not all, divisions of a client, fluctuations in the number and status of available projects within such divisions can also have a material impact on revenues earned from such clients from year to year.

ICON, although domiciled in Ireland, reports its results in U.S. dollars. As a consequence, the results of our non-U.S. based operations, when translated into U.S. dollars, could be materially affected by fluctuations in exchange rates between the U.S. dollar and the currencies of those operations.

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In addition to translation exposures, we are also subject to transaction exposures because the currency in which contracts are priced can be different from the currencies in which costs relating to those contracts are incurred. We have twelve operations operating in U.S. dollars, five trading in Euros, three in pounds Sterling, and one each in Australian dollars, Singapore dollars, Yen, Israeli New Shekels, Latvian Lats, Swedish Krona, Argentine Peso, South African Rand, Indian Rupee, Russian Rouble, Canadian dollar, Hungarian Forint and Hong Kong dollar. Our operations in the United States are not materially exposed to such currency differences as the majority of our revenues and costs are in U.S. dollars. However, outside the United States the multinational nature of our activities means that contracts are usually priced in a single currency, most often pounds Sterling, U.S. dollars or Euros, while costs arise in a number of currencies, depending, among other things, on which of our offices provide staff for the contract, and the location of investigator sites. Although many such contracts benefit from some degree of natural hedging due to the matching of contract revenues and costs in the same currency, where costs are incurred in currencies other than those in which contracts are priced, fluctuations in the relative value of those currencies could have a material effect on ICON's results of operations. We regularly review our currency exposures and hedge a portion of these, using forward exchange contracts, where they are not covered by natural hedges.

We have received capital and revenue grants from Forbairt, an Irish government agency. We record capital grants as deferred income, which are credited to income on a basis consistent with the depreciation of the relevant asset. Grants relating to operating expenditures are credited to income in the period in which the related expenditure is charged. The capital grant agreements provide that in certain circumstances the grants received may be refundable in full. These circumstances include sale of the related asset, liquidation of ICON or failing to comply in other respects with the grant agreements. The operating expenditure grant agreements provide for repayment in the event of a downsizing calculated by reference to any reduction in employee numbers. We have not recognized any loss contingency having assessed as remote the likelihood of these events arising. Up to May 31, 2004, we have received \$2,506,507 and \$1,863,006 under capital grants and operating grants,

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respectively. Pursuant to the terms of the grant agreements we are restricted from distributing some of these amounts by way of dividend or otherwise.

As we conduct operations on a global basis, our effective tax rate has depended and will depend on the geographic distribution of our revenue and earnings among locations with varying tax rates. ICON's results of operations therefore may be affected by changes in the tax rates of the various jurisdictions. In particular, as the geographic mix of our results of operations among various tax jurisdictions changes, our effective tax rate may vary significantly from period to period.

Operating Results

The following table sets forth for the periods indicated certain financial data as a percentage of net revenue and the percentage change in these items compared to the prior comparable period. The trends illustrated in the following table may not be indicative of future results.

2002

2003

2004

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| | Percentage of Net Revenue | | |
|-------------------------------------|---------------------------|--------|--------|
| Net revenue | 100.0% | 100.0% | 100.0% |
| Costs and expenses: | | | |
| Direct costs | 53.3% | 54.2% | 54.7% |
| Selling, general and administrative | 31.3% | 31.5% | 29.9% |
| Depreciation | 3.8% | 3.3% | 3.8% |
| Income from operations | 11.6% | 11.0% | 11.6% |

Fiscal Year Ended May 31, 2004 Compared to Fiscal Year Ended May 31, 2003

Net revenue increased by \$71.2 million, or 31.5%, from \$225.7 million to \$296.9 million. This improvement arose through a combination of increased business from existing clients, business won from new clients and revenues from acquisitions not included in the comparative period. The additional revenues from these acquisitions (BPA, MCS, Medeval and GloboMax) amounted to \$24.5 million for the fiscal year ended May 31, 2004. Including the impact of acquisitions, revenues in the United States, Europe and the Rest of World grew by 16.8%, 65.6% and 76.4% respectively. In the twelve months to May 31, 2004, net revenue from our central laboratory business grew by 2.8% from \$26.2 million to \$26.9 million while our clinical research segment grew by 35.3% from \$199.6 million to \$270.0 million over the comparable period. The growth in net revenue in our clinical research segment and central laboratory is due to the expansion of our services to both existing and new clients, increased use of outsourcing by the Pharmaceutical, Biotechnology and Medical Device industries, an underlying increase in research and development spending and consolidation in the CRO industry.

Direct costs increased by \$40.2 million, or 32.8%, from \$122.4 million to \$162.6 million, primarily due to increased staff numbers needed to support increased project related activity and increased costs arising from the acquisitions amounting to \$13.2 million. Direct costs as a percentage of net revenue increased from 54.2% in the twelve months to May 31, 2003 to 54.7% in fiscal 2004.

Selling, general and administrative expenses increased by \$17.7 million, or 24.9%, from \$71.1 million to \$88.8 million. The increase in costs is due to the continued expansion of our operations and additional selling, general and administrative costs from acquisitions of \$9.5 million not included in the comparative period. As a percentage of net revenue, selling, general and administrative expenses, decreased from 31.5% in the twelve months to May 31, 2003 to 29.9% for the fiscal year ended May 31, 2004.

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Depreciation expense increased by \$3.9 million, or 52.9%, from \$7.3 million to \$11.2 million. This increase is due to the continued investment in facilities and information technology to support the growth in activity and in providing for future capacity and increased cost arising from acquisitions of \$0.6

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million. As a percentage of net revenue, depreciation increased from 3.3% of net revenues in the twelve months to May 31, 2003 to 3.8% for the fiscal year ended May 31, 2004.

Income from operations increased by \$9.5 million, or 37.9%, from \$24.9 million to \$34.4 million, including acquisitions. This improvement is due to increased levels of activity carried out across the Company together with the acquisitions of BPA, MCS, Medeval and GloboMax. As a percentage of net revenue, income from operations increased from 11.0% for the twelve months to May 31, 2003 to 11.6% of net revenues for the fiscal year ended May 31, 2004. For the fiscal year 2004, income from operations, as a percentage of net revenue for the central laboratory fell to (12.2)% from 0.4% in fiscal 2003 due to an expanded cost base. The central laboratory constitutes approximately 9% of our business. Operating margins for our clinical research segment increased from 12.4% in the twelve months to May 31, 2003, to 13.9% for the fiscal year ended May 31, 2004 due principally to improved staff utilization and enhanced leverage of our overhead costs.

Net interest income for the year ended May 31, 2004, was \$0.3 million, a decrease of \$0.1 million on the equivalent period last year due primarily to lower than average interest rates during the current fiscal year.

ICON's effective tax rate for the year ended May 31, 2004, was 25.8% compared with 27.7% for the comparable period last year. The decrease in the effective rate was primarily due to a change in the geographic distribution of pre-tax earnings.

Fiscal Year Ended May 31, 2003 Compared to Fiscal Year Ended May 31, 2002

Net revenue increased by \$69.1 million, or 44.2%, from \$156.6 million to \$225.7 million. This improvement arose through a combination of increased business from existing clients, business won from new clients and revenues from acquisitions not included in the comparative period. The additional revenues from these acquisitions (BPA, MCS and Medeval) amounted to \$18.1 million for the fiscal year ended May 31, 2003. Including the impact of acquisitions, revenues in the United States and Europe/Rest of World grew by 47.6% and 36.7%, respectively. In the twelve months to May 31, 2003, net revenue from our central laboratory business grew by 1.1% from \$25.9 million to \$26.2 million while our clinical research segment grew by 52.7% from \$130.7 million to \$199.6 million over the comparable period. The growth in net revenue in our clinical research segment and central laboratory is due to the expansion of our services to both existing and new clients, increased use of outsourcing by the Pharmaceutical and Biotechnology industries, an underlying increase in research and development spending and consolidation in the CRO industry.

Direct costs increased by \$39.0 million, or 46.8%, from \$83.4 million to \$122.4 million, primarily due to increased staff numbers needed to support increased project related activity and increased costs arising from the acquisitions amounting to \$11.1 million. Direct costs as a percentage of net revenue increased from 53.3% in the twelve months to May 31, 2002 to 54.2% in the fiscal 2003.

Selling, general and administrative expenses increased by \$22.2 million, or 45.3%, from \$48.9 million to \$71.1 million. The increase in costs is due to the continued expansion of our operations and additional selling, general and administrative costs from acquisitions of \$5.4 million not included in the comparative period. As a percentage of net revenue, selling, general and administrative expenses, increased from 31.3% in the twelve months to May 31, 2002 to 31.5% for the fiscal year ended May 31, 2003.

Depreciation expense increased by \$1.3 million, or 21.3%, from \$6.0 million to \$7.3 million. This increase is due to the continued investment in facilities and

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information technology to support the growth in activity and in providing for future capacity and increased cost arising from acquisitions of \$0.2 million. As a percentage of net revenue, depreciation and amortization decreased from 3.8% of net revenues in the twelve months to May 31, 2002 to 3.3% for the fiscal year ended May 31, 2003.

Income from operations increased by \$6.7 million, or 36.9%, from \$18.2 million to \$24.9 million, including acquisitions. This improvement is due to increased levels of activity carried out across the Company together with the acquisition of BPA,

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MCS and Medeval. As a percentage of net revenue, income from operations decreased from 11.6% for the twelve months to May 31, 2002 to 11.0% of net revenues for the fiscal year ended May 31, 2003. For the fiscal year 2003, income from operations, as a percentage of net revenue for the central laboratory fell to 0.4% from 14.1% in fiscal 2002, due principally to a higher than normal level of project cancellations in the first quarter of fiscal 2003. Operating margins for our clinical research segment increased from 11.1% in the twelve months to May 31, 2002, to 12.4% for the fiscal year ended May 31, 2003 due principally to improved staff utilization.

Net interest income for the year ended May 31, 2003, was \$0.4 million, a decrease of \$0.8 million on the equivalent period last year due primarily to reduced cash on deposit and lower interest rates during the current fiscal year as cash was used to fund expansion and acquisition.

ICON's effective tax rate for the year ended May 31, 2003, was 27.7% compared with 26.5% for the comparable period last year. The increase in the effective rate was primarily due to a change in the geographic distribution of pre-tax earnings.

Liquidity and Capital Resources

The CRO industry generally is not capital intensive. Since our inception, we have financed our operations and growth primarily with cash flows from operations, net proceeds of \$49.1 million raised in our initial public offering in May 1998 and net proceeds of \$44.3 million, raised in our secondary offering in August 2003. Our principal cash needs are payment of salaries, office rents, travel expenditures and payments to investigators. The aggregate amount of employee compensation, excluding stock compensation expense, paid by us and our subsidiaries in the three fiscal years ended May 31, 2002, 2003 and 2004, amounted to \$88.2 million, \$135.2 million, and \$174.5 million, respectively. Investing activities primarily reflect capital expenditures for facilities, information systems enhancements, the purchase of short-term investments and acquisitions.

Our clinical research and development contracts are generally fixed price with some variable components and range in duration from a few months to several years. Revenue from contracts is generally recognized as income on the basis of the relationship between time incurred and the total estimated contract duration or on a fee-for-service basis. The cash flow from contracts typically consists of a down payment of between 10% and 20% paid at the time the contract is entered into, with the balance paid in installments over the contract's duration, in some cases on the achievement of certain milestones. Accordingly, cash receipts do not correspond to costs incurred and revenue recognized on contracts.

As of May 31, 2004, our working capital was \$113.8 million, compared to \$53.8

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million at May 31, 2003. The most significant influence on our operating cash flow is revenue outstanding, which comprises accounts receivable and unbilled revenue, less payments on account. The dollar values of these amounts and the related days revenue outstanding can vary due to the achievement of contractual milestones, including contract signing, and the timing of cash receipts. The number of days revenue outstanding was 60 days at May 31, 2004, 64 days at May 31, 2003 and 67 days at May 31, 2002. The decrease from May 31, 2003 to May 31, 2004, was due primarily to increased cash collections, as a result of a more stringent application of our trading terms with respect to our accounts receivable.

Net cash provided by operating activities was \$43.6 million in the year ended May 31, 2004, compared with \$21.5 million in fiscal 2003 and \$17.3 million in the fiscal year ended May 31, 2002. The increase in cash provided in fiscal 2004 was due primarily to improved cash collections and increased profitability.

Net cash used in investing activities was \$47.3 million in the year ended May 31, 2004, compared with \$35.3 million in the year ended May 31, 2003 and net cash provided by investing activities of \$4.8 million in the year ended May 31, 2002. This increase in net cash used is due principally to acquisition activity in the current fiscal year and purchase of short-term investments.

Net cash provided by financing activities was \$42.5 million in the year ended May 31, 2004, compared with net cash used in financing activities of \$4.6 million in fiscal 2003 and net cash provided by financing activities of \$2.7 million in the fiscal year ended May 31, 2002. The main reason for this increase is the receipt of the net proceeds of \$44.3 million, following the issue of 1,500,000 American Depositary Shares by the Company in August 2003.

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As a result of these cash flows, cash and cash equivalents increased by \$37.4 million in the year ended May 31, 2004, compared to a net decrease of \$18.0 million in the year ended May 31, 2003 and a net increase of \$25.1 million in the year ended May 31, 2004.

The Company entered into an overdraft agreement with Allied Irish Banks, plc ("AIB") whereby the company guarantees any overdraft of the subsidiary ICON Clinical Research GmbH up to an amount (euro)120,000 (U.S.\$146,604). As of May 31, 2004, the full facility was available to be drawn down.

The Company also entered into an overdraft agreement with AIB, whereby the company guaranteed any overdraft of the subsidiary ICON Clinical Research Israel Ltd. up to an amount of U.S.\$250,000. This facility was terminated on April 20, 2004.

On November 17, 1998, we entered into an overdraft facility (the "AIB facility") for (euro)2,539,000 (\$3,101,896) with AIB. This facility bore an annual interest rate equal to AIB Bank's Prime Rate plus one-quarter of one percent. The full sum of the unpaid principal and interest was repayable on demand. This facility was terminated on July 3, 2003.

On July 29, 2002, we entered into an additional AIB facility for STG(pound)50,000 (\$91,664) This facility bore interest at an annual rate equal to AIB Bank's Prime Rate plus two percent. The full sum of the unpaid principal and interest was repayable on demand. This facility was terminated on July 3, 2003.

Our U.S. subsidiary, ICON Clinical Research, Inc. (the "Borrower"), had a \$12

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million secured line of credit (the "PNC Facility") with PNC Bank N.A. ("PNC"). The PNC Facility bore interest at an annual rate equal to PNC's Prime Rate less three-quarters of one percent. The full sum of the unpaid principal and interest was payable on demand. The PNC Facility was secured by a first priority security interest in certain assets of the Borrower. This facility was terminated on July 3, 2003.

On July 3, 2003, ICON entered into a facility agreement (the "Facility Agreement") for the provision of a term loan facility of U.S.\$40 million, multi-currency overdraft facility of \$5 million; and revolving credit facility of \$15 million (the "Facilities") with The Governor and Company of the Bank of Ireland and Ulster Bank Ireland Limited (the "Banks"). Our obligations under the Facilities are secured by certain composite guarantees and indemnities and pledges in favour of each of the banks. This facility bears interest at an annual rate equal to the Banks Prime Rate plus three quarters of one percent. ICON plc and its subsidiaries are entitled to make borrowings under a term loan facility of \$40 million and a multi currency overdraft facility of \$5 million. As at May 31, 2004, the full amount of these facilities were available to be drawn down. ICON Clinical Research, Inc. (a subsidiary of ICON plc) is entitled to make borrowings under a revolving credit facility of \$15 million. As at May 31, 2004, the full amount of this facility was available to be drawn down.

On September 9, 2003, we completed the acquisition of Globomax LLC, for an initial cash consideration of \$10.9 million. Earn-out provisions have been built into the acquisition contract requiring the potential payment of additional deferred consideration up to a maximum of U.S.\$4.0 million depending on the performance of Globomax over the period from date of acquisition to May 31, 2006.

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Contractual obligations table

The following table represents the contractual obligations and commercial commitments of ICON plc as of May 31, 2004:

| | Payments due by period | | | |
|-----------------------------|------------------------|---------------------|-----------------|-----------------|
| | Total | Less than 1 year | 1 to 3 years | 3 to 5 years |
| Contractual obligations | | | | |
| Long-Term Debt Obligations | | | | |
| Capital Lease Obligations | \$0.4 | \$0.3 | \$0.1 | - |
| Operating lease Obligations | 147.9 | 21.9 | 33.7 | 26.3 |
| Purchase Obligations (1) | 4.5 | - | 4.5 | - |
| ----- | | | | |
| Total (U.S.\$ in millions) | \$152.8 | \$22.2 | \$38.3 | \$26.3 |
| ----- | | | | |

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(1) This figure consists of \$2.0 million payable under earn out clauses included in acquisitions undertaken in fiscal 2004 and the remaining \$2.5 million relating to prior period acquisitions. Of the \$4.5 million, \$2.5 million of the earn out targets have been reached at May 31, 2004 and has been recorded in other liabilities.

We expect to spend approximately \$15 million in the next twelve months on further investments in information technology, the expansion of existing facilities and the addition of new offices and expect to increase this level of spending in subsequent years. We believe that we will be able to fund our additional foreseeable cash needs for the next twelve months from cash flow from operations and existing cash balances. In the future, we will consider acquiring businesses to enhance our service offerings and global presence. Any such acquisitions may require additional external financing and we may from time to time seek to obtain funds from public or private issues of equity or debt securities. There can be no assurance that such financing will be available on terms acceptable to ICON.

Critical Accounting Policies

The preparation of consolidated financial statements in accordance with generally accepted accounting principles in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reported period.

We base our estimates and judgements on historical experience and on the other factors that we believe are reasonable under current circumstances. Actual results may differ from these estimates if these assumptions prove to be incorrect or if conditions develop other than as assumed for the purposes of such estimates. The following is a discussion of the accounting policies used by us, which we believe are critical in that they require estimates and judgements by management.

Revenue Recognition

Significant management judgements and estimates must be made and used in connection with the recognition of revenue in any accounting period. Material differences in the amount of revenue in any given period may result if these judgements or estimates prove to be incorrect or if management's estimates change on the basis of development of the business or market conditions. To date there has been no material differences arising from these judgements and estimates.

We earn revenues by providing a number of different services to our clients. These services include clinical trials management, biometric activities, consulting and laboratory services. We recognize biometric, consulting and laboratory revenues on a fee-for-service basis. Our laboratory service contracts are multiple element arrangements, with laboratory kits

and laboratory testing representing the contractual elements. We determine the fair values for these elements, each of which can be sold separately, based on objective and reliable evidence of their respective fair values. Our laboratory

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contracts entitle us to receive non-refundable set up fees and we allocate such fees as additional consideration to the contractual elements based on the proportionate fair values of the elements. We recognize revenues for the elements on the basis of the number of deliverable units completed in a period.

We recognize clinical trials revenue on the basis of the relationship between time incurred and the total estimated duration of the contract as this represents the most accurate pattern over which our contractual obligations are fulfilled. We invoice our customers upon achievement of specified contractual milestones. This mechanism, which allows us to receive payment from our customers throughout the duration of the contract, is not reflective of revenue earned. We recognize revenues over the period from the awarding of the customer's contract to study completion and acceptance. This requires us to estimate total expected revenue, time inputs, contract costs, profitability and expected duration of the clinical trial. These estimates are reviewed periodically and, if any of these estimates change or actual results differ from expected results, then an adjustment is recorded in the period in which they become readily estimable.

If we do not accurately estimate the resources required or the scope of the work to be performed, or do not manage our projects properly within the planned cost or satisfy our obligations under the contracts, then future results may be significantly and negatively affected.

Goodwill

The principal judgements and uncertainties affecting our accounting for goodwill relate to carrying values. The carrying values of purchased goodwill are assessed annually, using discounted cash flows and net realisable values. The estimates and judgements used to assess carrying values include those relating to commercial risk, revenue and cost projections, our intention with respect to the acquired goodwill, the impact of competition, the impact of any reorganisation or change of our business focus, the level of third party interest in our operations and market conditions.

If the implied fair value of reporting unit goodwill is lower than its carrying amount, goodwill is impaired and written down to its implied fair value. If we were to use different estimates or judgements, particularly with respect to expected revenue and cost projections or the impact of any reorganisation or change of business focus, a material impairment charge to the statement of operations could arise. We believe that we have used reasonable estimates and judgements in assessing the carrying value of our goodwill.

Inflation

We believe that the effects of inflation generally do not have a material adverse impact on our operations or financial conditions.

New Accounting Pronouncements

In December 2003, the FASB issued Interpretation No. 46, revised--Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51 ("FIN 46R"). FIN 46R addresses the consolidation of variable interest entities ("VIEs"), which include entities that have one or more of the following characteristics: (1) The equity investment at risk is not sufficient to permit the entity to finance its activities without additional subordinated financial support; (2) The equity investors lack essential characteristics of a controlling financial interest (as defined by FIN 46R); and (3) The equity investors have voting rights that are

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not proportionate to their economic interests, and the activities of the entity involve or are conducted on behalf of an investor with a disproportionately small voting interest. In addition, FIN 46R provides for certain scope exceptions to its application. Adoption of this Interpretation is required in financial statements that have interests in VIEs or potential VIEs, commonly referred to as special-purpose entities, for periods ending after 15 December 2003. Application for all other types of entities is required in financial statements for periods ending after 15 March 2004. The adoption of FIN 46R has not had a material impact on the Company's Consolidated Financial Statements.

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On April 30, 2003, the FASB issued FASB Statement No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities, which amends FASB Statement No. 133, Accounting for Derivative Instruments and Hedging Activities, to address (1) decisions reached by the Derivatives Implementation Group, (2) developments in other Board projects that address financial instruments, and (3) implementation issues related to the definition of a derivative. Statement 149 has multiple effective date provisions depending on the nature of the amendment to Statement 133. Under SFAS No. 133, our foreign exchange contracts do not qualify for hedge accounting treatment. The adoption of SFAS No.149 did not have a significant impact on our financial statements.

On May 15, 2003, the FASB issued FASB Statement No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity". This Statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003, except for certain mandatorily redeemable financial instruments. It is to be implemented by reporting the cumulative effect of a change in an accounting principle for financial instruments created before the issuance date of the Statement and still existing at the beginning of the interim period of adoption. Restatement is not permitted. The adoption of SFAS No.150 did not have a significant impact on our financial statements.

The Emerging Issues Task Force (EITF) has reached a final consensus on EITF Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. This Issue addresses certain aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities, specifically how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting. The Issue also addresses how arrangement consideration should be measured and allocated to the separate units of accounting in the arrangement. The guidance in this Issue is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003, with a possible alternative means of adoption by applying the new rules to existing contracts and recording the effect of adoption as a cumulative effect of a change in accounting principle. Early adoption is permitted. We adopted EITF Issue No. 00-21 on June 1, 2003. The adoptions of EITF Issue No. 00-21 did not have a significant impact on our financial statements.

In December 2003, the FASB issued SFAS Statement No. 132 (revised), "Employers' Disclosures about Pensions and Other Postretirement Benefits" ("SFAS No. 132 (revised)"). SFAS No. 132 (revised) will revise employers' disclosures about pension plans and other postretirement benefit plans. It does not change the measurement or recognition of those plans. SFAS No. 132 (revised) will retain

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and revise the disclosure requirements contained in the original SFAS No. 132. It also requires additional disclosures about the assets, obligations, cash flows, and net periodic benefit cost of defined benefit pension plans and other postretirement benefit plans. The Statement generally is effective for fiscal years ending after December 15, 2003. SFAS No. 132 did not have a material impact on the Company's Consolidated Financial Statements.

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Item 6. Directors, Senior Management and Employees.

Directors and Senior Management

The following table and accompanying biographies set forth certain information concerning each of ICON plc directors, officers and other key employees as of May 31, 2004.

| Name | Age | Position |
|----------------------------|-----|--|
| Dr. John Climax(1) (2) (5) | 51 | Chairman of the Board |
| Peter Gray(1) | 49 | Chief Executive Officer, Director |
| Sean Leech(1) | 33 | Chief Financial Officer |
| Dr. Ronan Lambe(1) | 64 | Director |
| Thomas Lynch(2) (3) (4) | 47 | Director |
| Edward Roberts(2) (3) (4) | 69 | Director |
| Lee Jones(3) (4) (6) | 48 | Director |
| Shuji Higuchi | 64 | Director |
| William Taaffe | 55 | President & Chief Executive Officer of ICON Clinical Research - U.S. |
| Dr. Peter Sowood | 51 | President of ICON Clinical Research - Europe |
| Edward Caffrey | 50 | President of ICON Laboratories |
| Dr. Dan Weng | 41 | President of ICON Clinical Research - Rest of World |
| Dr. John Hubbard | 47 | Chief Operating Officer, ICON Clinical Research - U.S. |
| Dr. Thomas Frey | 51 | Chief Operating Officer, ICON Clinical Research - Europe |
| Josephine Coyle | 46 | Vice President for Corporate Quality Assurance |

- (1) Executive Officer of the Company.
- (2) Member of Compensation Committee.
- (3) Member of Audit Committee.
- (4) Member of Nomination Committee.
- (5) Resigned from the Compensation Committee on July 22, 2004. (6) Joined the Compensation Committee on July 22, 2004.

Dr. John Climax, one of the Company's co-founders, has served as a director of the Company and its subsidiaries since June 1990. Dr. Climax served as Chief Executive Officer from June 1990 to October 2002 and was appointed Chairman of the Board in November 2002. Dr. Climax has over 19 years of experience in the contract research industry in both Europe and the United States. Dr. Climax received his primary degree in pharmacy in 1977 from the University of Singapore, his masters in applied pharmacology in 1979 from the University of Wales and his Ph.D. in pharmacology from the National University of Ireland in 1982.

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Peter Gray has served as the Chief Executive Officer of ICON and its subsidiaries since November 2002. He served as the Group Chief Operating Officer of ICON and its subsidiaries from June 2001, and was Chief Financial Officer from June 1997 to June 2001. He has been a director of the Company since June 1997. Mr. Gray has over 13 years experience in the pharmaceutical services industry and has also worked in the engineering and food sectors. Mr. Gray received a degree in Law from Trinity College Dublin in 1977 and became a chartered accountant in 1980.

Sean Leech has served as Chief Financial Officer of ICON and its subsidiaries since June 2001 and previously as Group Vice President of Finance from June 1999. Mr. Leech was Group Financial Controller of Jones Group plc, a shipping, manufacturing and fuel distribution company based in Ireland, from 1997 to 1999. Mr. Leech is an Associate member of the Chartered Institute of Management Accountants.

Dr. Ronan Lambe, one of the Company's co-founders, served as Chairman of the Board of the Company from June 1990 to November 2002. Dr. Lambe has over 22 years of experience in the contract research industry in Europe. Dr. Lambe attended

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the National University of Ireland where he received his bachelor of science degree in chemistry in 1959, his masters in biochemistry in 1962 and his Ph.D. in pharmacology in 1976. Dr. Lambe continues to serve as a director of the Company.

Thomas Lynch has served as an outside director of the Company since January 1996. Since May 1993, Mr. Lynch has held several senior positions in Elan Corporation, plc, a specialty pharmaceutical company, including Executive Vice President, Chief Financial Officer and Deputy Chairman. He is currently Senior Advisor to the Chairman of the Board of Elan Corporation plc. Mr. Lynch is a director of Nanogen, Inc. and Chairman of Amarin Corporation plc. Mr. Lynch was a partner at KPMG from May 1990 to May 1993.

Edward Roberts has served as an outside director of the Company since February 1998. Mr. Roberts was Managing Director of the Pharmaceutical Division of Merck KGaA from 1990 to 1998. Prior to that, he held a number of senior management positions with Eli Lilly International in Europe and the United States. Mr. Roberts has over 39 years of experience in the pharmaceutical industry. He has been a partner in Global Health Care Partners since June 1998, and also serves as Chairman of Biopartners and Chairman of the Advisory Board of Merz & Co. GmbH.

Lee Jones has served as an outside director of the Company since June 1, 2001. Since March 2000, he has been Chairman and Chief Executive Officer of Americas Doctor, a pharmaceutical services company. Previously, he was Divisional Vice-President of Information Management and Technology in the Pharmaceutical Product Division of Abbott Laboratories. He has held various senior positions with Abbott Laboratories and the Upjohn Company.

Mr. Shuji Higuchi has served as an outside Director of the Company since September 2004. Dr. Higuchi has over 39 years of experience in the pharmaceutical industry. Dr. Higuchi is currently Director of R&D and Business Integration, Kyoto University Hospital, Japan. Prior to this Dr. Higuchi has served as President of Takeda Pharma GmbH from 1983 to 1992, President of Takeda Europe R&D Centre, Frankfurt / London from 1992 to 2002, and served as a

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Corporate Officer of Takeda Chemical Industries Limited, Japan from 1999 to 2002.

William Taaffe has served as President of ICON Clinical Research - U.S. since November 1993 and now also holds the title of Chief Executive Officer of ICON Clinical Research - U.S. Mr. Taaffe has over 28 years of experience in the contract research and the pharmaceutical industries in Ireland, Canada and the United States. Mr. Taaffe received his bachelor of science degree in 1970 from the University College Dublin.

Dr. Peter Sowood, has served the company as President of ICON Clinical Research Europe since November 2003. Prior to joining the Company, Dr. Sowood held various positions at Covance Clinical and Periapproval Services, Ltd., including the position of Vice-president Clinical Research. Dr. Sowood was educated at the University of Cambridge in Medical Sciences and followed on to Oxford University where he took Medical Degrees before joining the RAF as a Medical Officer. Dr. Sowood obtained his PhD in 1988 and MBA in 1993.

Edward Caffrey has served as President of ICON Laboratories since June 2000. Mr. Caffrey has over 22 years experience in the contract research industry. From January 1998 until joining ICON, Mr. Caffrey was Senior Vice President of Clinical Operations at Covance North America; he also served as a Managing Director at Covance from January 1990 to January 1998. Mr. Caffrey is a fellow of the Institute of Biomedical Sciences in London and holds an MSc from Dublin City University.

Dr. Dan Weng, has served as President of ICON Clinical Research Rest of World since April 2004, having previously held the position of Senior Vice President - Rest of World since joining the Company in January 2003. Dr. Weng previously worked in the Asia Pacific region for both Pharmanet and Quintiles. Prior to joining the CRO industry in 1997, Dr. Weng worked in the US at the Harvard Medical School and at UCSF. Educated as a physician in China, Dr. Weng subsequently obtained an MBA and a PhD in the UK.

Dr. John W. Hubbard has served as Chief Operating Officer of ICON Clinical Research - U.S. since October 1999. Dr. Hubbard has more than 19 years of experience in pharmaceutical research and development. From July 1997 until joining ICON, he held the position of Senior Vice President of Clinical Research Operations at Clinical Studies, a division of

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Innovative Clinical Solutions, Ltd. Dr. Hubbard received a Ph.D. in Cardiovascular Physiology from the University of Tennessee and a B.S. in Psychology/Biology from the University of Santa Clara.

Dr. Thomas Frey has served as Chief Operating Officer for ICON Clinical Research Europe since June 2001 and previously served as Vice President of ICON Clinical Operations Europe from January 2000 to May 2001. Dr. Frey has 16 years of experience in pharmaceutical research and development. He started his career in 1987 with Hoechst Pharmaceuticals. From 1995 to the end of 1999 he was Senior Director of Clinical Development Europe at Hoechst Marion Roussel. Dr. Frey received his medical degree in 1980 from the University of Heidelberg.

Josephine Coyle has served as Vice President for Corporate Quality Assurance since April 2000. Ms. Coyle has held positions of increasing responsibility in ICON since August 1992 and previously held the position of director of Quality Assurance.

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Board of Directors

ICON's Articles of Association provide that, unless otherwise determined by ICON at a general meeting, the number of directors shall not be more than 15 nor less than 3. At each annual general meeting, one third of the directors who are subject to retirement by rotation, rounded down to the next whole number if it is a fractional number, shall retire from office. The directors to retire shall be those who have been longest in office, but as between persons who became or were last re-appointed on the same day, those to retire shall be determined, unless otherwise agreed, by lot. Accordingly, at the annual general meeting of ICON to be held in 2005, it is anticipated that three directors will retire by rotation and offer themselves for re-election, such directors to be determined, unless otherwise agreed, by lot. Any additional director appointed by us shall hold office until the next annual general meeting and will be subject to re-election at that meeting.

Board committees

We established a compensation committee and an audit committee in 1998 and the nominating committee in 2004, all of which are committees of the Board of Directors and are composed mainly of non-executive directors of ICON plc.

Compensation committee

The compensation committee comprises Thomas Lynch (Chairman), Edward Roberts and Lee Jones. It deals with all aspects of senior executive remuneration. The committee aims to ensure that remuneration packages are competitive so that individuals are appropriately rewarded relative to their responsibility, experience and value to ICON.

Annual bonuses for executive directors are determined by the committee based on the achievement of ICON's objectives.

Audit committee

The audit committee comprises Edward Roberts (Chairman), Thomas Lynch and Lee Jones. It reviews the annual report, the quarterly earnings releases, the effectiveness of the system of internal controls, reviews the compliance with our ethical code and legal requirements and approves the appointment and removal of the external auditors. It also addresses all issues raised and recommendations made by the external auditors and pre-approve all auditor services.

Nomination committee

The Nominating Committee comprises Thomas Lynch, Edward Roberts and Lee Jones. On an ongoing basis it reviews the membership of the board of directors, board committees and the performance of the directors and management. It identifies and recommends individuals to fill any vacancy that is anticipated or arises on the board of directors. It reviews and recommends the corporate governance principles of the Company. The nominating committee held one formal meeting during 2004.

The aggregate compensation paid by ICON to all persons who served in the capacity of director or executive officer in fiscal 2004 (8 persons) was approximately \$2.2 million, but does not include expenses reimbursed to officers (including business travel, professional and business association dues and expenses). As of May 31, 2004, options granted to directors and executive officers of ICON to purchase an aggregate of 82,400 of our ordinary shares were outstanding. The options are exercisable at prices between \$18.00 and \$42.15 and expire between May 15, 2006 and February 4, 2012.

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In addition, our officers are eligible to participate in ICON's Incentive Share Option Scheme. See Note 9 to the Consolidated Financial Statements.

Employees

We employed 2,432, 2,280 and 1,637 people for the years ending May 31, 2004, 2003 and 2002, respectively. Our employees are not unionized and we believe that our relations with our employees are good.

Share Ownership

The following table sets forth certain information regarding beneficial ownership of ICON's ordinary shares (including ADSs) as of July 23, 2004 by all of our current directors and executive officers. Unless otherwise indicated below, to our knowledge, all persons listed below have sole voting and investment power with respect to their ordinary shares, except to the extent authority is shared by spouses under applicable law.

| Name of Owner or Identity of Group | No. of Shares (1) | Options |
|------------------------------------|-------------------|---------|
| Dr. Ronan Lambe | 1,107,170 | 6,000 |
| Dr. John Climax | 1,556,892 | 15,000 |
| Mr. Peter Gray | 54,220 | 15,000 |
| Mr. Sean Leech | - | 18,400 |
| Mr. Thomas Lynch | 40,001 | 12,500 |
| Mr. Edward Roberts | 1 | 8,500 |
| Mr. Lee Jones | - | 5,500 |
| Mr. Shugi Higuchi | - | 1,500 |

- (1) As used in this table, each person has the sole or shared power to vote or direct the voting of a security, or the sole or shared investment power with respect to a security (i.e. the power to dispose, or direct the disposition, of a security). A person is deemed as of any date to have "beneficial ownership" of any security if that such person has the right to acquire such security within 60 days after such date.

Employee Share Option Schemes

On January 17, 2003, we adopted the Share Option Plan 2003, or the 2003 Plan, pursuant to which the Compensation Committee of the Board may grant options to employees of the Company or its subsidiaries for the purchase of ordinary shares. Each option will be either an incentive stock option, or ISO, described in Section 422 of the Code or an employee stock option, or NSO, not described in Section 422 or 423 of the Code. Each grant of an option under the 2003 Plan will be evidenced by a Stock Option Agreement between the optionee and the Company. The exercise price will be specified in each Stock Option Agreement, however option prices for an ISO will not be less than 100% of the fair market value of an ordinary share on the date the option is granted.

An aggregate of 1.5 million ordinary shares have been reserved under the 2003 Plan; and, in no event will the number of ordinary shares that may be issued pursuant to options awarded under the 2003 Plan exceed 10% of the outstanding shares, as defined in the 2003 Plan, at the time of the grant. Further, the maximum number of ordinary shares with respect to which options may be granted under the 2003 Plan during any calendar year to any employee shall be 100,000 ordinary shares.

No options can be granted after January 17, 2013.

Executive officers and Directors remuneration

For the year ended May 31, 2004, the total remuneration paid to our directors and executive officers including salary, bonus, pension and benefits-in-kind (2003: \$2,437,294), was as follows:

| | U.S.\$ |
|--------------------|-------------|
| ----- | ----- |
| Dr. John Climax | 734,470 |
| Dr. Ronan Lambe | 284,111 |
| Mr. Peter Gray | 578,550 |
| Mr. Sean Leech | 308,367 |
| Mr. Lee Jones | 28,750 |
| Mr. Edward Roberts | 43,750 |
| Mr. Thomas Lynch | 32,500 |
| Mr. Shugi Higuchi | 25,000 |
| Total | \$2,035,499 |

Item 7. Major Shareholders and Related Party Transactions.

- (a) ICON plc, is not directly or indirectly, owned or controlled by another corporation or by any government.
- (b) The following table sets forth certain information regarding beneficial ownership of ICON's ordinary shares (including ADS's) as of July 23, 2004 (i) by each person that beneficially owns more than 5% of the outstanding ordinary shares, based upon publicly available information; and (ii) by all of our current directors and executive officers as a group. Unless otherwise indicated below, to our knowledge, all persons listed below have sole voting and investment power with respect to their ordinary shares, except to the extent authority is shared by spouses under applicable law.

| Name of Owner or Identity of Group | No. of Shares (1) |
|--|-------------------|
| ----- | ----- |
| Wasatch Group Companies (3) | 2,201,659 |
| Dr. John Climax (2) | 1,571,892 |
| Fidelity Group Companies (3) | 1,404,294 |
| Dr. Ronan Lambe | 1,113,170 |
| Morgan Stanley Group Companies (3) | 851,500 |
| All officers and executive officers as a group (4) | 2,969,014 |

- (1) As used in this table, each person has the sole or shared power to vote or direct the voting of a security, or the sole or shared investment power with respect to a security (i.e., the power to dispose, or direct the disposition, of a security). A person is deemed as of any date to have "beneficial ownership" of any security if that such person has the right to acquire such security within 60 days after such date.
- (2) Includes 1,556,852 ADSs held by Poplar Limited, a Jersey company

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controlled by Dr. Climax.

- (3) Neither the Company nor any of its officers, directors or affiliates hold any voting power in this entity.
- (4) Includes 210,730 ordinary shares issuable upon the exercise of stock options granted by the Company.

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Related Parties

On February 6, 1998, ICON entered into an Option Agreement ("The Put Option") with Rosa Investment Limited ("Rosa"). Rosa's sole activity was to hold an investment in Clear Investments Limited ("Clear"), the sole activity of which was to hold Mr. Gray's option to exercise 54,000 ordinary shares. Mr. Gray is a director of Rosa and Clear. Rosa is owned by a trust of which Mr. Gray is a beneficiary. On April 21, 2004, Mr. Gray acquired Clear from Rosa and exercised the Put Option in accordance with the terms of the Option Agreement. On April 22, 2004, pursuant to the Option Agreement, ICON purchased the outstanding share capital in Clear from Mr. Gray, the consideration for the acquisition being the issuance of 54,000 fully paid up ordinary shares in ICON, to Mr. Gray, such a sale being the economic equivalent of Mr. Gray exercising his stock options.

Item 8. Financial Information.

Financial Statements

See item 18.

Legal Proceedings

ICON is not party to any litigation or other legal proceedings that we believe could reasonably be expected to have a material adverse effect on our business, results of operations and financial condition.

Dividends

We have not paid cash dividends on our ordinary shares and do not intend to pay cash dividends on our ordinary shares in the foreseeable future.

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Item 9. The Offer and the Listing.

ICON's ADSs are traded on the Nasdaq National Market under the symbol "ICLR". Our Depository for the ADSs is The Bank of New York. ICON also has a secondary listing on the Official List of the Irish Stock Exchange. No securities of ICON are traded in any other market. The following table sets forth the trading price for the dates indicated for ICON plc ADSs as reported by Nasdaq.

| Year Ending | High Sales Price During Period | Low Sales Price During Period |
|--------------|-----------------------------------|----------------------------------|
| May 31, 1999 | \$36.75 | \$10.00 |
| May 31, 2000 | \$29.00 | \$11.87 |

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| | | |
|--------------|---------|---------|
| May 31, 2001 | \$29.75 | \$15.00 |
| May 31, 2002 | \$39.58 | \$22.93 |
| May 31, 2003 | \$32.87 | \$14.88 |
| May 31, 2004 | \$46.05 | \$25.87 |

| Quarter Ending | High Sales Price During Period | Low Sales Price During Period |
|----------------|-----------------------------------|----------------------------------|
| May 31, 2001 | \$27.55 | \$18.38 |
| Aug 31, 2001 | \$39.58 | \$26.74 |
| Nov 30, 2001 | \$35.69 | \$22.93 |
| Feb 28, 2002 | \$32.79 | \$25.13 |
| May 31, 2002 | \$34.49 | \$23.87 |
| Aug 31, 2002 | \$30.50 | \$14.88 |
| Nov 30, 2002 | \$26.00 | \$18.99 |
| Feb 28, 2003 | \$32.87 | \$22.35 |
| May 31, 2003 | \$30.85 | \$21.36 |
| Aug 31, 2003 | \$36.80 | \$25.87 |
| Nov 30, 2003 | \$45.04 | \$31.20 |
| Feb 29, 2004 | \$46.05 | \$33.03 |
| May 31, 2004 | \$43.49 | \$29.74 |

| Month Ending | High Sales Price During Period | Low Sales Price During Period |
|----------------|-----------------------------------|----------------------------------|
| Dec 31, 2003 | \$45.17 | \$40.30 |
| Jan 31, 2004 | \$46.05 | \$34.55 |
| Feb 29, 2004 | \$38.95 | \$33.03 |
| March 31, 2004 | \$37.20 | \$29.74 |
| April 30, 2004 | \$43.49 | \$35.44 |
| May 31, 2004 | \$42.03 | \$36.71 |

Item 10. Additional Information.

Memorandum and Articles of Association

On January 12, 2004, at ICON's Annual General Meeting, the Articles of Association of ICON plc were amended to accommodate the electronic communication with shareholders. The following amendments were made:

(a) The Amendment of Article 1 through the deletion of the definition of "the Acts" and the insertion of the following new definitions:

| | |
|---------------------------------|--|
| "the Acts" | the Companies Acts, 1963 to 2003 and every statutory modification or re-enactment thereof for the time being in effect; |
| "Address" | includes any number or address used for the purposes of communication by way of electronic mail or other Electronic Communication; |
| "Advanced Electronic Signature" | has the same meaning as under the Electronic Commerce Act, 2000 (as amended or supplemented from time to |

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time);

"Electronic
Communication"

has the same meaning as under the
Electronic Commerce Act, 2000 (as
amended or supplemented from time to
time);

"Electronic

Signature" has the same meaning as under
the Electronic Commerce Act, 2000 (as
amended or supplemented from time to
time);

"in writing"

written, printed, photographed or
lithographed or visibly expressed in
all or any of those or any other modes
of representing or reproducing words
provided that it shall not include
writing in electronic form except as
provided in these Articles and/or where
it constitutes writing in electronic
form sent to either the Company
or a member of the Company, the Company
or member of the Company has agreed to
receipt in such form;

- (b) by the insertion of the following words in the fourth line of Article 33, after the words "in writing" :

"(including writing in electronic form)"

- (c) by the insertion of the following words in the last line of Article 105, after the word "documents":

"(including by means of Electronic Communication)"

- (d) by the insertion of the following words in the second line of Article 125, after the words "in writing":

"or by sending the same by electronic mail or other form of Electronic Communication approved by the Directors to the address of any Member notified to the Company by the Member for such purpose."

- (e) by the insertion of the following sub-paragraph (a)(iv) in Article 126:

"if by sending the same by electronic mail or by other form of Electronic Communication approved by the Directors to the address of a Member notified to the Company by the Member for such purpose."

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- (f) by the insertion of the following additional sentence at the end of sub-section (c) of Article 126:

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"Where a notice or document is given, served or delivered pursuant to sub-paragraph (iv) of this Article, the giving, service or delivery thereof shall be deemed to have been effected at the expiration of forty-eight (48) hours after the dispatch of the Electronic Communication and a transaction report shall be conclusive evidence thereof."

- (g) by the amendment of sub paragraph (e) of Article 126 so that the first two lines now read as follows:

"Without prejudice to the provisions of sub-paragraph (a)(i), (ii) and (iv) of this..."

- (h) by the insertion of the following into Article 127, between the words "address" and "but":

"or shall be entitled to receive notices by electronic mail, or other formal Electronic Communication approved by the Directors, to be sent to an address notified to the Company by the Member for such purpose"

- (i) by the insertion of the following into Article 128, between the words "Share" and "and":

"or, in the case of a notice sent by electronic mail or other form of Electronic Communication approved by the Directors, to the address in respect of the Joint Holding notified to the Company by the Joint Holders for such purpose,"

- (j) by the insertion of the following into Article 129(b), between the words "address" and "if":

"(inclusive of an electronic address)"

- (k) by the inclusion of the following words at the end of Article 130:

"or, in the case of a notice in electronic form the signature may be an Electronic Signature, Advanced Electronic Signature or otherwise as the Directors may approve."

Exchange Controls and Other Limitations Affecting Security Holders.

Irish exchange control regulations ceased to apply from and after December 31, 1992. Except as indicated below, there are no restrictions on non-residents of Ireland dealing in domestic securities, which includes shares or depository receipts of Irish companies such as ICON. Except as indicated below, dividends and redemption proceeds also continue to be freely transferable to non-resident holders of such securities.

The Financial Transfers Act, 1992 gives power to the Minister for Finance of Ireland to make provision for the restriction of financial transfers between Ireland and other countries. Financial transfers are broadly defined, and include all transfers, which would be movements of capital or payments within the meaning of the treaties governing the European Communities. The acquisition or disposal of ADRs representing shares issued by an Irish incorporated company and associated payments may fall within this definition. In addition, dividends or payments on redemption or purchase of shares and payments on a liquidation of an Irish incorporated company would fall within this definition. At present, the

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Financial Transfers Act, 1992 prohibits financial transfers only to, or by the order of, or on behalf of, listed terrorist organizations, also listed residents and entities of Zimbabwe and Burma/Myanmar without the prior permission of the Central Bank of Ireland.

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Any transfer of, or payment in respect of an ADS involving the government of any country which is currently the subject of United Nations sanctions, any person or body controlled by any of the foregoing, or by any person acting on behalf of the foregoing, may be subject to restrictions pursuant to such sanctions as implemented into Irish law. There are no restrictions under ICON's Articles of Association, or under Irish Law, that limit the right of non-residents or foreign owners to hold or vote the ordinary shares.

Taxation

General

The following discussion is based on existing Irish tax law, Irish court decisions and the practice of the Revenue Commissioners of Ireland, and the convention between the United States and Ireland for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to income and capital gains (the "Treaty"). This discussion does not purport to deal with the tax consequences of owning the ordinary shares for all categories of investors, some of which may be subject to special rules. Prospective purchasers of ordinary shares are advised to consult their own tax advisors concerning the overall tax consequences arising in their own particular situations under Irish law. Each prospective investor should understand that future legislative, administrative and judicial changes could modify the tax consequences described below, possibly with retroactive effect.

As used herein, the term "U.S. Holder" means a beneficial owner of ordinary shares that (i) owns the ordinary shares as capital assets; (ii) is a U.S. citizen or resident, a U.S. corporation, an estate the income of which is subject to U.S. federal income taxation regardless of its source or a trust that meets the following two tests: (A) a U.S. court is able to exercise primary supervision over the administration of the trust, and (B) one or more U.S. persons have the authority to control all substantial decisions of the trust; and for purposes of the discussion under Irish Taxation of U.S. Holders (A) is not a resident of, or ordinarily resident in, Ireland for the purposes of Irish tax; and (B) is not engaged in trade or business in Ireland through a permanent establishment.

AS USED HEREIN, REFERENCES TO THE ORDINARY SHARES SHALL INCLUDE ADSs REPRESENTING SUCH ORDINARY SHARES AND ADRs EVIDENCING OWNERSHIP OF SUCH ADSs.

Irish Taxation

ICON is a public limited company incorporated and resident for tax purposes in Ireland.

For Irish tax purposes, the residence of a company is in the jurisdiction where the central management and control of the company is located. Subject to certain exceptions, all Irish incorporated companies are deemed to be Irish tax resident. Companies which are resident in the Republic of Ireland are subject to Irish corporation tax on their total profits (wherever arising and, generally, whether or not remitted to the Republic of Ireland). The question of residence, by virtue of management and control, is essentially one of fact. It is the

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present intention of the company's management to continue to manage and control the company from the Republic of Ireland, so that the company will continue to be resident in the Republic of Ireland.

The standard rate of Irish corporation tax on trading income (with certain exceptions) is currently 12.5%.

Patent exemption is available to Irish resident companies whose income derives from qualifying royalties or license fees paid in respect of qualifying patents. The main requirement to qualify for the exemption is that the research, planning, processing, experimentation, testing, devising, designing, developing or similar activity leading to the invention which is the subject of the patent is carried out in Ireland. Under Irish law, income from such qualifying patents is disregarded for taxation purposes. There is no termination date for this relief specified in the legislation.

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To the extent that the company is involved in the "manufacture" of goods in Ireland, income from this activity, in respect of its data processing operations carried out in Ireland, can qualify for a 10% rate of tax. This relief is available until December 31, 2010.

Corporation tax is charged at the rate of 25% on a company's non-trading income and certain types of trading income not eligible for the lower rates discussed above.

Irish capital duty, a tax on the issuance of share capital by companies, is payable at the rate of 1% of proceeds received by the company in consideration of such issuance.

Taxation of Dividends

Unless exempted, all dividends paid by ICON, other than dividends paid entirely out of exempt patent income (subject to conditions), will be subject to Irish withholding tax at the standard rate of income tax in force at the time the dividend is paid, currently 20%. An individual shareholder who is neither resident nor ordinarily resident for tax purposes in Ireland, but is resident in a country with which Ireland has a double tax treaty, which includes the United States, or in a member state of the European Union, other than Ireland (together a "Relevant Territory"), will be exempt from withholding tax provided he or she makes the requisite declaration. No dividend withholding tax will apply on the payment of a dividend from an Irish resident company to its Irish resident 51% parent company. Where the Irish company receiving the dividend does not hold at least 51% of the shares of the paying company, the dividend will be exempt if the Irish corporate shareholder makes the requisite declaration.

Non-Irish resident corporate shareholders that:

- o are ultimately controlled by residents of a Relevant Territory;
- o are resident in a Relevant Territory and are not controlled by Irish residents;
- o have the principal class of their shares, or shares of a 75% parent, substantially and regularly traded on one or more recognized stock exchanges in a Relevant Territory or Territories; or

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- o are wholly owned by two or more companies, each of whose principal class of shares is substantially and regularly traded on one or more recognized stock exchanges in a Relevant Territory or Territories;

will be exempt from withholding tax on the production of the appropriate certificates and declarations.

U.S. Holders of ordinary shares (as opposed to ADSs: see below) should note, however, that these documentation requirements may be burdensome. As described below, these documentation requirements do not apply in the case of ADSs.

Special arrangements are available in the case of shares held in Irish companies through American depositary banks using ADSs. The depositary bank will be allowed to receive and pass on a dividend from the Irish company without any deduction for withholding tax in the following circumstances:

- o the depositary has been authorized by the Irish Revenue Commissioners as a qualifying intermediary and such authorization has not expired or revoked; and either
- o the depositary bank's ADS register shows that the beneficial owner has a U.S. address on the register; or
- o if there is a further intermediary between the depositary bank and the beneficial owner, where the depositary bank receives confirmation from the intermediary that the beneficial owner's address in the intermediary's records is in the U.S.

Income Tax

Under certain circumstances, non-Irish resident shareholders will be subject to Irish income tax on dividend income. This liability is limited to tax at the standard rate and therefore, where withholding tax has been deducted, this will satisfy the tax

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liability.

However, a U.S. Holder will not have an Irish income tax liability on dividends from the company if the U.S. Holder is neither resident nor ordinarily resident in the Republic of Ireland and the U.S. Holder is:

- o an individual resident in the U.S. (or several other countries);
- o a corporation that is ultimately controlled by persons resident in the U.S. (or several other countries);
- o a corporation whose principal class of shares (or its 75% or greater parent's principal class of shares) is substantially and regularly traded on a recognized stock exchange in an EU country or a country with which Ireland has concluded a double taxation treaty;
- o a corporation resident in another EU member state or in a country with which Ireland has concluded a double taxation treaty, which is not controlled directly or indirectly by Irish residents; or

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- o a corporation that is wholly owned by two or more corporations each of whose principal class of shares is substantially and regularly traded on a recognized stock exchange in an EU country or a country with which Ireland has concluded a double taxation treaty.

U.S. Holders that do not fulfill the documentation requirements or otherwise do not qualify for the withholding tax exemption may be able to claim treaty benefits under the treaty. U.S. Holders that are entitled to benefits under the treaty will be able to claim a partial refund of the 20% withholding tax from the Irish Revenue Commissioners.

Taxation of Capital Gains

A person who is not resident or ordinarily resident in Ireland, has not been an Irish resident within the past five years and who does not carry on a trade in Ireland through a branch or agency will not be subject to Irish capital gains tax on the disposal of ordinary shares or ADSs, so long as the ordinary shares or ADSs, as the case may be, are either quoted on a stock exchange or do not derive the greater part of their value from Irish land or mineral rights. There are provisions to subject a person who disposes of an interest in a company while temporarily non-resident in the Republic of Ireland, to Irish capital gains tax. This treatment will apply to individuals who:

- o cease to be Irish resident;
- o own the shares when they cease to be resident;
- o resume their Irish residence within five years;
- o dispose of an interest in a company during this temporary non-residence; and
- o the interest disposed of represents 5% or greater of the share capital of the company or is worth at least (euro)500,000.

In these circumstances the person will be deemed, for Irish capital gains tax purposes, to have sold and immediately reacquired the interest in the company on the date of his or her departure and will be subject to tax at 20% of the taxable gain.

Irish Capital Acquisitions Tax

Irish capital acquisitions tax (referred to as CAT) applies to gifts and inheritances.

Where a gift or inheritance is taken under a disposition made after December 1, 1999, it will be within the charge to CAT:

- o to the extent that the property of which the gift or inheritance consists is situated in the Republic of Ireland at the date of the gift or inheritance;
- o where the person making the gift or inheritance is or was resident or ordinarily resident in the Republic of Ireland at the date of the disposition under which the gift or inheritance is taken;

- o in the case of a gift taken under a discretionary trust where the person from whom the gift is taken was resident or ordinarily resident in the Republic of Ireland at the date he made the settlement, or at

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- the date of the gift or, if he is dead at the date of the gift, at his death; or
- o where the person receiving the gift or inheritance is resident or ordinarily resident in the Republic of Ireland at the date of the gift or inheritance.

Where a gift or an inheritance is taken under a disposition made prior to December 1, 1999, CAT is chargeable in the following circumstances:

- o to the extent that the property of which the gift or inheritance consists is situated in the Republic of Ireland at the date of the gift or inheritance;
- o where the person making the gift or inheritance is or was domiciled in Ireland at the date of the disposition under which the gift or inheritance is taken;
- o in the case of a gift taken under a discretionary trust, where the disposer, who is usually the settlor, in relation to that trust was domiciled in Ireland at the date he made the settlement, or at the date of the gift or, where the gift is taken after his death, at the date of his death.

The person who receives the gift or inheritance is primarily liable for CAT. A person is secondarily liable if he is the donor, his personal representative or an agent, trustee or other person in whose care the property constituting the gift or inheritance or the income therefrom is placed. Taxable gifts or inheritances received by an individual since December 5, 1991 from donors in the same threshold class are aggregated and only the excess over a specified tax-free threshold is taxed. The tax-free threshold is dependent on the relationship between the donor and the donees and the aggregation since December 5, 1991 of all previous gifts and inheritances, within the same tax threshold.

The tax-free threshold amounts currently in force are:

- o (euro)22,822 in the case of persons who are not related to one another;
- o (euro)45,644 in the case of gifts or inheritances received from inter alia a brother or sister or from a brother or sister of a parent or from a grandparent; and
- o (euro)456,438 in the case of gifts and inheritances received from a parent (or from a grandparent by a minor child of a deceased child) and specified inheritances received by a parent from a child.

Gifts and inheritances passing between spouses are exempt from CAT.

A gift or inheritance of ordinary shares or ADSs will be within the charge to Irish capital acquisitions tax, notwithstanding that the person from whom or by whom the gift or inheritance is received is domiciled or resident outside Ireland.

The Estate Tax Convention between Ireland and the United States generally provides for Irish capital acquisitions tax paid on inheritances in Ireland to be credited against U.S. federal estate tax payable in the United States and for tax paid in the United States to be credited against tax payable in Ireland, based on priority rules set forth in the Estate Tax Convention. The Estate Tax Convention does not apply to Irish capital acquisitions tax paid on gifts.

Irish Probate Tax

Irish probate tax was abolished under the Finance Act, 2001. No probate tax will arise on any assets passing in respect of a death occurring on or after December 6, 2000.

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Irish Stamp Duty - Ordinary Shares

Irish stamp duty, which is a tax on certain documents, including CREST operator instructions, is payable on all transfers of the ordinary shares (other than between spouses) whenever a document of transfer is executed. Where the transfer is attributable to a sale, stamp duty will be charged at a rate of 1%, rounded to the nearest Euro. The stamp duty is calculated on the amount or value of the consideration (i.e. purchase price) or, if the transfer is by way of a gift (subject to certain exceptions) or for consideration less than the market value, on the market value of the shares. Where the consideration for the sale is expressed in a currency other than Euro, the duty will be charged on the Euro equivalent calculated at the rate of exchange prevailing on the date of the transfer.

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Transfers of ordinary shares between associated companies (broadly, companies within a 90% group relationship, and subject to the satisfaction of certain conditions) are exempt from stamp duty in the Republic of Ireland. In the case of transfers of ordinary shares where no beneficial interest passes (e.g. a transfer of shares from a beneficial owner to his nominee), no stamp duty arises where the transfer contains the appropriate certificate and, in the absence of such certificate, a flat rate of (euro)12.70 (the nominal rate) will apply.

Irish Stamp Duty - ADSs Representing Ordinary Shares

A transfer by a shareholder to the depositary or custodian of ordinary shares for deposit under the deposit agreement in return for ADSs and a transfer of ordinary shares from the depositary or the custodian upon surrender of ADSs for the purposes of the withdrawal of the underlying ordinary shares in accordance with the terms of the deposit agreement will be stampable at the ad valorem rate if the transfer relates to a sale or contemplated sale or any other change in the beneficial ownership of such ordinary shares. However, it is not certain whether the mere withdrawal of ordinary shares in exchange for ADSs or ADSs for ordinary shares would be deemed to be a transfer of or change in the beneficial ownership which would be subject to stamp duty at the ad valorem rate. Where the transfer merely relates to a transfer where no change in the beneficial ownership in the underlying ordinary shares is effected or contemplated, no stamp duty arises where the transfer contains the appropriate certificate and, in the absence of such certificate, the nominal rate stamp duty of (euro)12.70 applies.

Transfers of ADSs are exempt from Irish stamp duty as long as the ADSs are dealt in on the Nasdaq National Market or any recognized stock exchange in the United States or Canada.

The person accountable for payment of stamp duty is the transferee or, in the case of a transfer by way of gift, or for a consideration less than the market value, all parties to the transfer. A late or inadequate payment of stamp duty will result in a liability to pay interest, penalties and fines.

Documents on Display

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, and file reports and other information with the SEC. You may read and copy any of our reports and other information at, and obtain copies upon payment of prescribed fees from, the Public Reference Room maintained by the SEC at 450 Fifth Street, N.W., Room 1024, Washington, D.C. 20549 and at the

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SEC's regional office at Northwestern Atrium Center, 500 West Madison Street, Suite 1400, Chicago, IL 60661. In addition, the SEC maintains a Web site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC at <http://www.sec.gov>. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

We "incorporate by reference" information that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this report and more recent information automatically updates and supersedes more dated information contained or incorporated by reference in this report. Our SEC file number is 333-8704.

As a foreign private issuer, we are exempt from the rules under the Securities Exchange Act of 1934, as amended, prescribing the furnishing and content of proxy statements to shareholders.

We will provide without charge to each person, including any beneficial owner, on the written or oral request of such person, a copy of any or all documents referred to above which have been or may be incorporated by reference in this report (not including exhibits to such incorporated information that are not specifically incorporated by reference into such information). Requests for such copies should be directed to us at the following address: ICON plc, South County Business Park, Leopardstown, Dublin 18, Ireland, Attention: Brian O'Dwyer, telephone number: (353) 1 291 2000.

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Item 11. Quantitative and Qualitative Disclosures about Market Risk.

Qualitative Disclosure of Market Risk. The principal market risks (i.e. risk of loss arising from adverse changes in market rates and prices) to which we are exposed are:

- o Interest rate changes on short term investments (available for sale) in the form of floating rate notes and medium term minimum "A" rated corporate securities, and
- o Foreign currency risk on non-U.S. dollar denominated cash and non-U.S. dollar denominated debt.

We use derivative financial instruments solely to hedge exposure to these market risks and we do not enter into these instruments for trading or speculative purposes.

Our primary foreign currency exchange risk relates to movements in rates between the U.S. dollar, Sterling and the Euro. At May 31, 2004, we had cash denominated in non-U.S. dollar denominated currencies. In order to reduce the foreign currency exchange risk during the year, we entered into certain derivative instruments to reduce our exposure to adverse changes in exchange rates. These financial instruments comprised of a series of foreign exchange forward contracts all of which were settled during the 2004 fiscal year. At May 31, 2004, we held no foreign exchange forward contracts.

Quantitative disclosure of Market Risk. The analysis below presents the sensitivity of the market value, or fair value of our financial instruments to selected changes in market rates and prices. The changes chosen represent our

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view of changes that are reasonable over a one year period. The estimated fair value of the foreign exchange forward contracts is based on quotations from independent third party financial institutions.

The hypothetical changes in fair value are estimated based on the same methodology used by the third party financial institutions to calculate the fair value of the original instruments, keeping all variables constant except the relevant exchange rate, as the case may be, which has been adjusted to reflect the hypothetical change. Fair value estimates by their nature are subjective and involve uncertainties and matters of significant judgment and therefore cannot be determined precisely.

Foreign Currency Exchange Risk

The sensitivity analysis below represents the hypothetical change in fair value based on an immediate 10% movement in the exchange rates.

| | Fair value at May 31, 2004 (in thousands) | Fair value Change +10% movement in foreign exchange rate (in thousands) |
|--|---|--|
| Non-U.S. Dollar denominated cash | \$17,877 | \$1,788 |
| Non-U.S. Dollar denominated short term debt | - | - |

Item 12. Description of Securities Other than Equity Securities.

Not applicable.

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Part II

Item 13. Defaults, Dividend Arrearages and Delinquencies.

None.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds.

None.

Item 15. Controls and Procedures

(a) Evaluation of disclosure controls and procedures.

At the end of the fiscal year, an evaluation was carried out under the

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supervision and with the participation of the Company's management, including the Chief Executive Officer (CEO) and the Chief Financial Officer (CFO), of the effectiveness of our disclosure controls and procedures. Based on that evaluation, the CEO and CFO have concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

(b) Changes in internal controls.

The CEO and CFO have concluded there were no significant changes in the Company's internal controls or in the other factors that could significantly affect those controls subsequent to the date of their evaluation.

Item 16. Reserved.

A. Audit Committee Financial Expert

During fiscal year 2004 the Company named Mr. Thomas Lynch, as an audit committee financial expert serving on its audit committee and board of directors. Mr. Lynch is independent and serves as one of the company's non-executive directors.

B. Code of Ethics

The Company's Board of Directors adopted a code of ethics in 2003 that applies to the Chief Executive Officer, the Chief Financial Officer and any persons performing similar functions, if any, of the Company.

There are no material modifications to, or waivers from, the provisions of such code, which are required to be disclosed.

This code is available on the Company's website at the following address:

<http://www.iconclinical.com/index.asp?getpage=true&sid=1&ssid=0&sssid=0&page=17>

C. Principal Accountant Fees and Services

The Company's principal accountants for the years 2003 and 2004 were KPMG.

The table below summarizes the fees for professional services rendered by KPMG for the audit of the Company's annual financial statements for 2003 and 2004 and fees billed for other services rendered by KPMG.

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| | Year ended May 31st | | | |
|------------------------|------------------------|-----|------------------------|-----|
| | 2003 (in thousands) | % | 2004 (in thousands) | % |
| Audit fees (1) | \$554 | 51% | \$647 | 60% |
| Audit related fees (2) | 119 | 11% | 40 | 4% |
| Tax fees (3) | 392 | 36% | 369 | 34% |
| All other fees (4) | 17 | 2% | 19 | 2% |

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| | | | | |
|-------|---------|------|---------|------|
| Total | \$1,082 | 100% | \$1,075 | 100% |
|-------|---------|------|---------|------|

(1) Audit fees include annual audit fees for ICON plc and its subsidiaries as well as an audit for the registration statement filed in 2003.

(2) Audit related fees principally consisted of fees for financial due diligence services and fees for audit of financial statements of employee benefit plans.

(3) Tax fees are fees for tax compliance and tax consultation services.

(4) All other fees are fees for secretarial assistance and grant certifications rendered by the Company's auditors.

The Audit Committee pre-approves on an annual basis the audit and non-audit services provided to the Company by its auditors.

Such annual pre-approval is given with respect to particular services. The Audit Committee, on a case-by-case basis, may approve additional services not covered by the annual pre-approval, as the need for such services arises.

Part III

Item 17. Financial Statements.

Not applicable.

Item 18. Financial Statements.

Reference is made to pages 45 to 77 of this Form 20-F.

Item 19. Financial Statements and Exhibits.

Financial statements of ICON plc and subsidiaries

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets at May 31, 2003, and May 31, 2004

Consolidated Statements of Operations for the years ended May 31, 2002, 2003 and 2004

Consolidated Statements of Shareholders' Equity and Comprehensive Income for the years ended May 31, 2002, 2003 and 2004.

Consolidated Statements of Cash Flows for the years ended May 31, 2002, 2003 and 2004

Notes to the Consolidated Financial Statements

Exhibits of ICON plc and subsidiaries

Significant subsidiaries

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Section 906 certifications

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Directors and Shareholders of ICON plc

We have audited the accompanying consolidated balance sheets of ICON plc and subsidiaries as of May 31, 2003 and 2004 and the related consolidated statements of operations, shareholders' equity and comprehensive income and cash flows for each of the years in the three-year period ended May 31, 2004. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in Ireland and the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of ICON plc and subsidiaries as of May 31, 2003 and 2004, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended May 31, 2004 in conformity with accounting principles generally accepted in the United States.

KPMG
Public Accounting Firm

Dublin, Ireland
July 23, 2004

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ICON plc
CONSOLIDATED BALANCE SHEETS

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2003
(in thousands)

ASSETS

Current Assets:

| | |
|--|----------|
| Cash and cash equivalents | \$18,311 |
| Short term investments - available for sale (Note 3) | - |
| Accounts receivable | 74,645 |
| Unbilled revenue | 44,783 |
| Other receivables | 4,385 |
| Deferred tax asset (Note 12) | 32 |
| Prepayments and other current assets | 8,326 |

| | |
|----------------------|---------|
| Total current assets | 150,482 |
|----------------------|---------|

Other Assets:

| | |
|---|--------|
| Property, plant and equipment, net (Note 5) | 39,503 |
| Goodwill (Note 4) | 45,029 |

| | |
|--------------|-----------|
| Total Assets | \$235,014 |
|--------------|-----------|

LIABILITIES AND SHAREHOLDERS' EQUITY

Current Liabilities:

| | |
|---|----------|
| Accounts payable | \$11,092 |
| Payments on account | 45,763 |
| Other liabilities (Note 6) | 28,289 |
| Income taxes payable | 4,385 |
| Bank overdraft and loan facilities (Note 7) | 7,126 |

| | |
|---------------------------|--------|
| Total current liabilities | 96,655 |
|---------------------------|--------|

Other Liabilities:

| | |
|--|-------|
| Long term government grants (Note 10) | 1,140 |
| Long term finance leases | 309 |
| Non-current deferred tax liability (Note 12) | - |

Shareholders' Equity:

| | |
|--|--------|
| Ordinary shares, par value 6 Euro cents per share; 20,000,000 shares authorized, 11,841,557 shares issued and outstanding at May 31, 2003 and 13,838,476 shares issued and outstanding at May 31, 2004 (Note 11) | 841 |
| Additional paid-in capital | 61,164 |
| Accumulated other comprehensive income | 7,787 |
| Merger reserve | 47 |
| Retained earnings | 67,071 |

| | |
|----------------------------|---------|
| Total Shareholders' Equity | 136,910 |
|----------------------------|---------|

| | |
|--|-----------|
| Total Liabilities and Shareholders' Equity | \$235,014 |
|--|-----------|

The accompanying notes are an integral part of these consolidated financial statements.

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ICON plc
CONSOLIDATED STATEMENTS OF OPERATIONS

| | Year Ended | |
|---|------------------------------|------------|
| | 2002 | |
| | (in thousands, except share) | |
| ----- | | |
| Revenue: | | |
| Gross revenue | \$218,842 | \$340,000 |
| Subcontractor costs | (62,287) | (115,000) |
| ----- | | |
| Net revenue | 156,555 | 225,000 |
| Costs and expenses: | | |
| Direct costs | 83,371 | 122,000 |
| Selling, general and administrative | 48,951 | 71,000 |
| Depreciation and amortization | 6,020 | 7,000 |
| ----- | | |
| Total costs and expenses | 138,342 | 200,000 |
| ----- | | |
| Income from operations | 18,213 | 24,000 |
| Interest income | 1,603 | 1,000 |
| Interest expense | (487) | (1,000) |
| ----- | | |
| Income before provision for income taxes | 19,329 | 25,000 |
| Provision for income taxes (Note 12) | (5,129) | (7,000) |
| ----- | | |
| Net income | \$14,200 | \$18,000 |
| ----- | | |
| Net income per ordinary share: | | |
| Basic | \$1.22 | \$1.80 |
| ----- | | |
| Diluted | \$1.16 | \$1.70 |
| ----- | | |
| Weighted average number of ordinary shares outstanding: | | |
| Basic | 11,656,153 | 11,813,000 |
| ----- | | |
| Diluted | 12,241,820 | 12,181,000 |
| ----- | | |

The accompanying notes are an integral part of these consolidated financial statements.

ICON plc
 CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY AND COMPREHENSIVE INCOME

| | Shares | Amount | Additional Paid-in Capital (in thousands, | Accumulated Other Comprehensive Income except share and per | Ret Ear |
|------------------------------------|------------|--------|--|---|------------|
| Balance at May 31, 2001 | 11,429,629 | \$819 | \$56,537 | \$ (5,411) | \$3 |
| Comprehensive Income: | | | | | |
| Net income | - | - | - | - | 1 |
| Currency translation adjustment | - | - | - | 2,950 | |
| Total comprehensive income | | | | | |
| Exercise of share options | 358,100 | 19 | 2,655 | - | |
| Shares issued | 10,772 | 1 | 364 | - | |
| Tax benefit on exercise of options | - | - | 792 | - | |
| Balance at May 31, 2002 | 11,798,501 | \$839 | \$60,348 | \$ (2,461) | \$4 |
| Comprehensive Income: | | | | | |
| Net income | - | - | - | - | 1 |
| Currency translation adjustment | - | - | - | 10,248 | |
| Total comprehensive income | | | | | |
| Exercise of share options | 39,360 | 2 | 726 | - | |
| Shares issued | 3,696 | - | 77 | - | |
| Share issue costs | - | - | (35) | - | |
| Tax benefit on exercise of options | - | - | 48 | - | |
| Balance at May 31, 2003 | 11,841,557 | \$841 | \$61,164 | \$7,787 | \$6 |
| Comprehensive Income: | | | | | |
| Net income | - | - | - | - | 2 |
| Currency translation adjustment | - | - | - | 2,197 | |
| Total comprehensive income | | | | | |

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| | | | | |
|------------------------------------|------------|-------|-----------|---------|
| Exercise of share options | 496,919 | 35 | 5,323 | - |
| Shares issued | 1,500,000 | 104 | 45,601 | - |
| Share issue costs | - | - | (1,428) | - |
| Tax benefit on exercise of options | - | - | 2,276 | - |
| ----- | | | | |
| Balance at May 31, 2004 | 13,838,476 | \$980 | \$112,936 | \$9,984 |
| ----- | | | | |

The accompanying notes are an integral part of these consolidated financial statements.

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ICON plc
CONSOLIDATED STATEMENTS OF CASH FLOWS

| | 2002 | Year Ended 2001 (in thousands) |
|---|----------|--------------------------------------|
| Cash flows from operating activities: | | |
| Net income | \$14,200 | \$18,280 |
| Adjustments to reconcile net income to net cash (used in)/ provided by operating activities: | | |
| Loss on disposal of fixed assets | 46 | |
| Depreciation | 6,020 | 7,300 |
| Amortization of grants | (46) | (36) |
| Deferred taxes | 19 | 37 |
| Changes in assets and liabilities: | | |
| (Increase)/decrease in accounts receivable | (10,873) | (23,232) |
| Increase in unbilled revenue | (5,376) | (14,480) |
| Decrease in other receivables | 2,062 | 7,510 |
| Increase in prepayments and other current assets | (2,697) | (1,965) |
| Increase in payments on account | 8,655 | 25,480 |
| Increase/(decrease) in other liabilities | 731 | (1,787) |
| Increase in income taxes payable | 2,897 | 250 |
| Increase/(decrease) in accounts payable | 1,631 | 3,760 |
| ----- | | |
| Net cash provided by operating activities | 17,269 | 21,480 |
| Cash flows from investing activities: | | |
| Purchase of property, plant and equipment | (10,425) | (15,788) |
| Purchase of subsidiary undertakings and acquisition costs | - | (36,873) |
| Cash acquired with subsidiary undertakings | - | 1,910 |
| Deferred payments in respect of prior year acquisitions | (2,615) | (3,078) |
| Sale of short term investments | 29,868 | 18,550 |
| Purchase of short term investments | (12,478) | |
| Receipt of government grant | 464 | |
| ----- | | |
| Net cash provided by/(used in) investing activities | 4,814 | (35,278) |
| Cash flows from financing activities: | | |

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| | | |
|---|----------|----------|
| Proceeds from / (repayment of) bank overdraft | 547 | (5,319) |
| Repayment of long term debt | (338) | |
| Proceeds from exercise of share options | 2,674 | 69 |
| Proceeds from the issuance of share capital | - | |
| Share Issuance Costs | - | |
| Repayment of other liabilities | (165) | |
| ----- | | |
| Net cash provided by / (used in) financing activities | 2,718 | (4,626) |
| Effect of exchange rate movements on cash | 311 | 43 |
| ----- | | |
| Net increase/ (decrease) in cash and cash equivalents | 25,112 | (17,980) |
| Cash and cash equivalents at beginning of year | 11,179 | 36,29 |
| ----- | | |
| Cash and cash equivalents at end of year | \$36,291 | \$18,31 |
| ----- | | |

The accompanying notes are an integral part of these consolidated financial statements.

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ICON plc NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. Description of business

ICON plc and subsidiaries ("The Company") is a Contract Research Organization ("CRO") providing clinical research and development services on a global basis to the pharmaceutical, biotechnology and medical device industries. The Company specializes in the management, execution and analysis of complex, multinational clinical trials in most major therapeutic areas. The Company believes that it is one of a select group of CROs with the capability and expertise to conduct clinical trials on a global basis. As of May 31, 2004, the Company had approximately 2,450 employees and operations in 35 locations in 21 countries, including the United States and major markets in Europe and Rest of World and has managed clinical trials in over 50 countries. For the fiscal year ended May 31, 2004, we derived approximately 62.4%, 34.0% and 3.6% of our net revenue in the United States, Europe and Rest of World, respectively.

2. Significant Accounting Policies

The accounting policies noted below were applied in the preparation of the accompanying financial statements of the Company and are in conformity with accounting principles generally accepted in the United States.

(a) Basis of consolidation

The consolidated financial statements include the financial statements of ICON plc and all of its subsidiaries. All significant intercompany profits, transactions and account balances have been eliminated. The results of subsidiary undertakings acquired in the year are included in the consolidated statement of operations from the date of acquisition.

(b) Use of estimates

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The preparation of financial statements in conformity with generally accepted accounting principles in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reported period. Actual results could differ from those estimates.

(c) Revenue recognition

The Company primarily earns revenues by providing a number of different services to its customers. These services include clinical trials management, biometric activities, consulting and laboratory services. Contracts range in duration from a number of months to several years.

Clinical trials management revenue is earned on the basis of the relationship between time incurred and the total estimated duration of the trial. Biometrics revenue is recognized on a fee-for-service method on the basis of the number of units completed in a period as a percentage of the total number of contracted units. Consulting revenue is recognized on a fee-for-service basis as the related service is performed. Laboratory service revenue is recognized on a fee-for-service basis. The Company accounts for laboratory service contracts as multiple element arrangements, with contractual elements comprising laboratory kits and laboratory testing, each of which can be sold separately. Fair values for contractual elements are determined by reference to objective and reliable evidence of their fair values. Non-refundable set-up fees are allocated as additional consideration to the contractual elements based on the proportionate fair values of each of these elements. Revenues for contractual elements are recognized on the basis of the number of deliverable units completed in the period.

Contracts generally contain provisions for renegotiation in the event of changes in the scope, nature, duration, volume of services or conditions of the contract. Renegotiated amounts are recognized as revenue by revision to the total contract value arising as a result of an authorized customer change order. Provisions for losses to be incurred on contracts are recognized in full in the period in which it is determined that a loss will result from performance of the contractual arrangement.

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The difference between the amount of revenue recognized and the amount billed on a particular contract is included in the balance sheet as unbilled revenue. Normally, amounts become billable upon the achievement of certain milestones, in accordance with pre-agreed payment schedules included in the contract or on submission of appropriate billing detail. Such cash payments are not representative of revenue earned on the contract as revenues are recognized over the period in which the specified contractual obligations are fulfilled. Amounts included in unbilled revenue are expected to be collected within one year and are included within current assets. Advance billings to customers, for which revenue has not been recognized, are recognized as payments on account within current liabilities.

In the event of contract termination, if the value of work performed and recognized as revenue is greater than aggregate milestone billings at the date of termination, cancellation clauses ensure that the Company is paid for all work performed to the termination date.

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(d) Subcontractor costs

Subcontractor costs comprise investigator payments and certain other costs which are reimbursed by clients under terms specific to each contract and are deducted from gross revenue in arriving at net revenue. Investigator payments are accrued based on patient enrollment over the life of the contract. Investigator payments are made based on predetermined contractual arrangements, which may differ from the accrual of the expense. Payments to investigators in excess of the accrued expense are classified as prepaid expenses and accrued expense in excess of amounts paid are classified as accounts payable.

(e) Direct costs

Direct costs consist of compensation and associated employee benefits for project-related employees and other direct project-related costs.

(f) Advertising costs

All costs associated with advertising and promotion are expensed as incurred. The advertising and promotion expense was U.S.\$988,000, U.S.\$1,336,000 and U.S.\$1,596,000 for the years ended May 31, 2002, 2003 and 2004 respectively.

(g) Foreign currencies and translation of subsidiaries

The Company's financial statements are prepared in United States dollars. Transactions in currencies other than United States dollars are recorded at the rate ruling at the date of the transactions. Monetary assets and liabilities denominated in currencies other than United States dollars are translated into United States dollars at exchange rates prevailing at the balance sheet date. Adjustments resulting from these translations are charged or credited to income and where material are separately disclosed. For the years ended May 31, 2002, 2003 and 2004 amounts charged/(credited) to income amounted to U.S.\$1,412,000, U.S.\$1,968,000 and (U.S.\$2,445,000) respectively.

The financial statements of subsidiaries with other functional currencies are translated at year end rates for the balance sheet and average rates for the income statement. Translation gains and losses arising are reported as a movement on accumulated other comprehensive income.

During the year, the Company entered into foreign exchange currency contracts to manage its exposure against currency fluctuations on anticipated Euro denominated cashflows. Currency gains and losses arising in the year under these arrangements are recorded in the statement of operations.

(h) Disclosure about fair value of financial instruments

The following methods and assumptions were used to estimate the fair value of each material class of financial instrument:

Cash, cash equivalents, unbilled revenue, other receivables, short term investments, prepayments and other current assets, accounts receivable, accounts payable, investigator payments, payments received on account, accrued liabilities, accrued

bonuses, bank overdraft and taxes payable carrying amount approximates fair value due to the short term maturities of these instruments.

Long-term debt and other liabilities carrying amounts approximate fair value

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based on net present value of estimated future cash flows.

(i) Leased Assets

Costs in respect of operating leases are charged to the statement of operations on a straight line basis over the lease term.

Assets acquired under capital finance leases are included in the balance sheet at the present value of the future minimum lease payments and are depreciated over the shorter of the lease term and their remaining useful lives. The corresponding liabilities are recorded in the balance sheet and the interest element of the capital lease rental is charged to interest expense.

(j) Goodwill

In July 2001, the Financial Accounting Standards Board (FASB) issued two new statements: SFAS No. 141, "Business Combinations", and Statement No. 142, "Goodwill and Other Intangible Assets". Those Statements changed the accounting for business combinations and goodwill in two significant ways. First, SFAS No. 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001. Use of the pooling-of-interests method is prohibited. Second, SFAS No.142 changes the accounting for goodwill from an amortization method to an impairment-only approach.

The Company adopted SFAS No.142 effective June 1, 2001 and ceased amortization of goodwill as of June 1, 2001. The Company does not have any intangible assets. SFAS No.142 requires a two step impairment test for goodwill. The first step is to compare the carrying amount of the reporting units' assets to the fair value of the reporting unit. If the carrying amount exceeds the fair value then a second step is required to be completed which involves the fair value of the reporting unit being allocated to each asset and liability with the excess being implied goodwill. The impairment loss is the amount by which the recorded goodwill exceeds the implied goodwill. The Company has completed its transitional and annual assessments of goodwill impairment and concluded that no indication of goodwill impairment existed at May 31, 2002, May 31, 2003 or 2004.

(k) Cash and cash equivalents

Cash and cash equivalents include cash and highly liquid investments with initial maturities of three months or less and is stated at cost, which approximates market value.

(l) Short term investments - available for sale

The Company has classified short-term investments as available for sale in accordance with the terms of SFAS No.115 "Accounting for Certain Investments in Debt and Equity Securities". Realized gains and losses are determined using specific identification. The investments are reported at fair value, with unrealized gains or losses reported in a separate component of shareholders' equity. Any differences between the cost and fair value of the investments are represented by accrued interest.

(m) Inventory

Inventory is valued at the lower of cost and net realizable value and after provisions for obsolescence. Cost in the case of raw materials comprises the purchase price and attributable costs, less trade discounts. Cost in the case of work in progress and finished goods, comprises fixed labor, raw materials costs and attributable overheads.

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(n) Property, plant and equipment

Property, plant and equipment are stated at cost less accumulated depreciation. Depreciation of property, plant and equipment is computed using the straight line method based on the estimated useful lives of the assets as listed below:

| | Years |
|---------------------------------|-------|
| Building | 40 |
| Computer equipment and software | 4 |
| Office furniture and fixtures | 8 |
| Laboratory equipment | 5 |
| Motor vehicles | 5 |

Leasehold improvements are amortized using the straight-line method over the estimated useful life of the asset or the lease term, whichever is shorter.

(o) Income taxes

The Company applies Statement of Financial Accounting Standard ("SFAS") No. 109, "Accounting for Income Taxes," which requires the asset and liability method of accounting for income taxes. Under the asset and liability method of SFAS No. 109, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which these temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognised in income in the period that includes the enactment date.

(p) Government grants

Government grants received relating to capital expenditure are shown as deferred income and credited to income on a basis consistent with the depreciation policy of the relevant assets.

Grants relating to categories of operating expenditures are credited to income in the period in which the expenditure to which they relate is charged.

Under the grant agreements amounts received may become repayable in full should certain circumstances specified within the grant agreements occur, including downsizing by the Company, disposing of the related assets, ceasing to carry on its business or the appointment of a receiver over any of its assets.

The Company has not recognized any loss contingency having assessed as remote the likelihood of these events arising.

(q) Pension costs

The Company contributes to defined contribution plans covering all eligible employees. The Company contributes to these plans based upon various fixed percentages of employee compensation and such contributions are expensed as incurred.

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The Company operates, through a subsidiary, a defined benefit plan for certain of its United Kingdom employees. The Company accounts for the costs of this plan using actuarial models required by SFAS No.87, "Employers Accounting for Pensions". Disclosures are presented in accordance with the requirements of SFAS No.132(R), "Employees' Disclosures about Pensions and Other Post-retirement Benefits".

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(r) Net income per ordinary share

Basic net income per ordinary share has been computed by dividing net income available to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period. Diluted net income per ordinary share is computed by adjusting the weighted average number of ordinary shares outstanding during the period for all potentially dilutive ordinary shares outstanding during the period and adjusting net income for any changes in income or loss that would result from the conversion of such potential ordinary shares.

There is no difference in net income used for basic and diluted net income per ordinary share. The reconciliation of the number of shares used in the computation of basic and diluted net income per ordinary share is as follows:

| | 2002 | Year Ended |
|--|------------|------------|
| Weighted average number of ordinary shares outstanding for basic net income per ordinary share | 11,656,153 | 11,813 |
| Effect of dilutive share options outstanding | 582,908 | 367 |
| Effect of dilutive shares to be issued as part of deferred consideration | 2,759 | |
| <hr/> | | |
| Weighted average number of ordinary shares for diluted net income per ordinary share | 12,241,820 | 12,181 |
| <hr/> | | |

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(s) Stock-based compensation

The Company accounts for its share options in accordance with the provisions of SFAS No. 123, "Accounting for Stock-Based Compensation". SFAS No. 123 allows

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entities to continue to apply the provisions of Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees", and provide pro forma net income and pro forma earnings per share disclosures for employee stock option grants as if the fair-value-based method defined in SFAS No. 123 had been applied. APB No. 25 permits entities to recognize as expense, over the vesting period, the fair value of all stock-based awards on the date of grant. The Company has elected to apply the provisions of APB Opinion No. 25 and provide the pro forma disclosure provisions of SFAS No. 123.

The following table illustrates the effect on net income and earnings per share as if the fair value method of SFAS No. 123 had been applied to all outstanding and unvested stock options in each period.

| | Year Ended | |
|---|------------|--------------------|
| | 2002 | |
| | | (in thousands) |
| | | (except per share) |
| Net income, as reported | \$14,200 | \$18,000 |
| Add: Stock-based employee compensation expense included in reported net income, net of related tax effects | - | - |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects | (1,609) | (2,000) |
| Pro forma net income | \$12,591 | \$16,000 |
| Earnings per share (in \$): | | |
| Basic - as reported | \$1.22 | \$1.50 |
| Basic - pro forma | 1.08 | 1.30 |
| Diluted - as reported | 1.16 | 1.40 |
| Diluted - pro forma | 1.03 | 1.25 |

(t) Impairment of long-lived assets

Long lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less selling costs.

3. Short term investments - available for sale

The Company has classified its entire investment portfolio comprising floating rate and medium term minimum "A" rated corporate securities, as available for sale. The investments are reported at fair value, with unrealized gains or losses reported in a separate component of shareholder equity. In the years to May 31, 2002, 2003 and 2004 no unrealized gains or losses arose. Any differences between the cost and fair value of the investments are represented by accrued interest.

4. Goodwill

| | Year Ended May 31 | |
|--|-------------------|----------|
| | 2003 | 2004 |
| | (in thousands) | |
| Opening Goodwill | \$10,093 | \$45,029 |
| Arising during the year | 32,302 | 13,000 |
| Arising on earn-out (current and prior year acquisitions)..... | 2,003 | 3,000 |
| Foreign exchange movement..... | 631 | 2,000 |
| ----- | | |
| Closing Goodwill..... | \$45,029 | \$64,226 |
| ----- | | |

The distribution of goodwill by business segment was as follows:

| | Year Ended May 31, | |
|--------------------|--------------------|----------|
| | 2003 | 2004 |
| | (in thousands) | |
| Central laboratory | \$ 6,596 | \$ 7,017 |
| Clinical research | 38,433 | 57,209 |
| ----- | | |
| Total | \$45,029 | \$64,226 |
| ----- | | |

(a) Acquisition of YRCR Ltd.

On January 27, 2000, the Company acquired YRCR Limited ("YRCR"), a U.K. based regulatory consultancy company. The Company acquired YRCR in exchange for cash of Stg(pound)500,000 (U.S.\$819,000) and 51,387 ordinary shares, the fair market value of which was Stg(pound)500,000 (U.S.\$819,000) on the date the contract terms were agreed, excluding costs of acquisition. The acquisition of YRCR has been accounted for as a purchase.

Earn-out provisions were built into the contract, over the period to May 2003 up to a maximum additional consideration of Stg(pound)2.0 million (U.S.\$2.9 million), with additional purchase consideration to be recorded as goodwill.

On April 3, 2000, an additional cash payment of Stg(pound)250,000 (U.S.\$393,043) was made to YRCR as part of the earn-out provision. On May 31, 2000, an additional 24,272 ordinary shares were issued to YRCR with a fair market value of Stg(pound)250,000 (U.S.\$367,500).

As part of the earn-out provisions, on August 31, 2001, an additional 10,772 ordinary shares were issued to YRCR with a fair market value of

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Stg(pound)250,000 (U.S.\$365,400), and, on September 3, 2001, an additional cash payment of Stg(pound)250,000 (U.S.\$365,400) was made. Of these amounts Stg(pound)400,000 (U.S.\$590,800) was provided at May 31, 2001, as the earn-out target had been reached, with the balance of Stg(pound)100,000 (U.S.\$140,000) accounted for during the year ended May 31, 2002.

On August 30, 2002, an additional cash payment of Stg(pound)50,000 (U.S.\$77,526) was made to YRCR and on October 8, 2002, an additional 3,696 ordinary shares were issued to YRCR with a fair market value of Stg(pound)50,000 (U.S.\$77,440) as part of the earn-out provisions. Both these earn out payments were accrued for at May 31, 2002 and paid for during the year ended May 31, 2002.

On December 30, 2003, a cash payment of Stg(pound)100,000 (U.S.\$176,897) was made to the former shareholders of YRCR Limited. This represents the final payment due to the former shareholders of YRCR under the acquisition contract.

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The initial purchase price of U.S.\$1,838,000 including costs of acquisition together with subsequent additional consideration of U.S.\$1,823,206 for YRCR was allocated as follows:

| | (in thousands) |
|------------------------------------|----------------|
| Property, plant and equipment..... | \$125 |
| Goodwill..... | 3,346 |
| Current assets..... | 879 |
| Accounts payable..... | (689) |
| ----- | |
| Purchase price..... | \$3,661 |
| ----- | |

(b) Acquisition of Protocole

On March 14, 2000, the Company acquired Protocole ("Protocole"), a Paris based veterinary CRO. The Company acquired Protocole for initial cash consideration of French Francs 4,000,000 (U.S.\$586,240), excluding costs of acquisition. Earn-out provisions have been built into the acquisition contract requiring the potential payment of additional deferred consideration up to a maximum of French Francs 4,000,000 depending on the performance of Protocole over the period to May 31, 2003. None of the earn-out provisions had been reached at May 31, 2003 and there are no further payments due under this agreement. The acquisition of Protocole has been accounted for as a purchase.

The purchase price of U.S.\$732,000 for Protocole was allocated as follows:

| | (in thousands) |
|------------------------------------|----------------|
| Property, plant and equipment..... | \$12 |
| Goodwill..... | 731 |
| Current assets..... | 114 |
| Current liabilities..... | (125) |
| ----- | |
| Purchase price..... | \$732 |

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(c) Acquisition of UCT (U.S.) Inc.

On June 8, 2000, the Company acquired UCT (U.S.) Inc. ("UCT"), subsequently renamed ICON Laboratories Inc., a central laboratory company based in New York, USA. The Company acquired UCT in exchange for cash of U.S.\$1,200,000. Earn-out provisions were built into the acquisition contract requiring the potential payment of additional deferred consideration of U.S.\$18 million depending on the performance of UCT over the period to May 31, 2003. The acquisition of UCT has been accounted for as a purchase. Additional consideration paid was in the form of cash and was accounted for as goodwill.

On September 1, 2001, an additional cash payment of U.S.\$2,250,000 was made to UCT as part of the earn-out provisions. The first earn-out target was reached as at May 31, 2001 and this consideration has been included in the purchase price below.

On August 30, 2002 the Company made a cash payment of U.S.\$3,000,000 to the former shareholders of UCT (U.S.) Inc., under the terms of an earn out provision entered into on the acquisition of UCT on June 8, 2000. The earn-out target was reached at May 31, 2002 and this consideration was recorded at that date in the financial statements.

On October 2, 2003, a cash payment of U.S.\$421,000 was made to the former shareholders of UCT (U.S.) Inc. as part of the earn-out provisions in the contract. This represents the final payment due to the former shareholders of UCT under the acquisition contract.

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The purchase price of U.S.\$7,424,000 including total earn-out provisions of U.S.\$5,671,000 and acquisition costs of U.S.\$553,000 was allocated as follows:

| | (in thousands) |
|------------------------------------|----------------|
| Property, plant and equipment..... | \$1,415 |
| Goodwill..... | 7,088 |
| Current assets..... | 4,276 |
| Accounts payable..... | (5,355) |
| ----- | |
| Purchase price..... | \$7,424 |
| ----- | |

(d) Acquisition of Barton & Polansky Associates, Inc. and Managed Clinical Solutions, Inc.

On October 9, 2002, the Company acquired 100% of the outstanding shares of Barton & Polansky Associates, Inc. ("BPA") and its sister company Managed

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Clinical Solutions, Inc. ("MCS"), both based in New York, USA, for an initial cash consideration of U.S.\$15.7 million, excluding costs of acquisition which amounted to U.S.\$0.8 million. Earn-out and working capital provisions have been built into the acquisition contract requiring the potential payment of additional deferred consideration up to a maximum of U.S.\$18 million depending on the performance of MCS over the period to May 31, 2006. Such potential additional consideration will be accounted for as goodwill. The total amount of goodwill is expected to be tax deductible.

On December 20, 2002, and April 15, 2003, additional cash payments of U.S.\$3.7 million and U.S.\$0.3 million respectively were made to the former shareholders of BPA and MCS as part of the working capital provisions in the contract. The acquisitions of BPA and MCS have been accounted for as a purchase in accordance with SFAS No.141 "Business Combinations".

On July 25, 2003, August 20, 2003, August 29, 2003 and September 11, 2003, additional cash payments totaling U.S.\$110,897 were made to the former shareholders of Barton & Polansky Associates, Inc. ("BPA") and Managed Clinical Solutions, Inc. ("MCS"), as part of the working capital provisions in the applicable acquisition contract.

The purchase price of U.S.\$16.5 million including costs of acquisition together with subsequent additional consideration of U.S.\$4.1 million was allocated as follows:

| | (in thousands) |
|-----------------------------|----------------|
| Property, plant & equipment | \$2 |
| Goodwill | 14,550 |
| Current assets | 9,533 |
| Bank overdraft | (700) |
| Current liabilities | (2,795) |
| ----- | |
| Purchase Price | \$20,590 |
| ----- | |

The results of BPA and MCS have been included in the consolidated financial statements from October 1, 2002.

(e) Acquisition of Medeval Group Ltd

On January 24, 2003, the Company acquired 100% of the outstanding shares of Medeval Group Limited ("Medeval"), a company based in Manchester, England, for an initial cash consideration of Stg(pound)9.5 million (U.S.\$15.5 million), excluding costs of acquisition which amounted to U.S.\$1.0 million. Earn-out provisions have been built into the acquisition contract requiring the potential payment of additional deferred consideration up to a maximum of Stg(pound)4.3 million (U.S.\$6.9 million) depending on the performance of Medeval over the period to May 31, 2004. Such additional consideration has been accounted for as goodwill.

On May 31, 2003, an amount of Stg(pound)1.4 million (U.S.\$2.0 million) was accrued in relation to the Medeval acquisition, as the first earn-out target identified in the acquisition contract was reached on this date. It was provided in the applicable acquisition agreement that the form of the earn-out would consist of cash payable to one specific named selling shareholder, with the balance due to the other selling shareholders being in the form of guaranteed

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loan notes. These guaranteed loan notes have a repayment date of three years from the date of issue but are exercisable six months from that date. On September 30, 2003, Stg(pound)0.472 million (U.S.\$0.8 million) was paid in cash to the specific named selling shareholder. On the same date, Stg(pound)0.753 million (U.S.\$1.403 million) of guaranteed loan notes were issued to the remaining selling shareholders and were included in other liabilities. The guaranteed loan note holders issued redemption notices to the Company, which will require the Company to redeem all the guaranteed loan notes on June 30, 2004, in consideration for a cash payment of Stg(pound)0.753 million (U.S.\$1.380 million), the total amount of which was accrued at May 31, 2004.

Stg(pound)1.367 million (U.S.\$2.5 million) was accrued at 31 May, 2004 in relation to the second earn-out target provided for in the contract and has been included in the purchase price below.

The acquisition of Medeval has been accounted for as a purchase in accordance with SFAS No. 141, "Business Combinations". The following table summarises the fair values of the assets acquired and the liabilities assumed at the date of acquisition.

| | (in thousands) |
|-------------------------------|----------------|
| Property, plant and equipment | \$1,632 |
| Goodwill | 22,372 |
| Current assets | 2,738 |
| Pension liabilities (note 6) | (2,588) |
| Other current liabilities | (3,113) |
| | |
| Purchase Price | \$21,041 |
| | |

The results of Medeval have been included in the consolidated financial statements from January 24, 2003.

(f) Acquisition of GloboMax LLC

On September 9, 2003, the Company acquired 100% of the outstanding shares of Globomax LLC, based in Maryland, USA, for an initial cash consideration of U.S.\$10.9 million, excluding costs of acquisition. Earn-out provisions have been built into the acquisition contract requiring the potential payment of additional deferred consideration up to a maximum of U.S.\$4.0 million depending on the performance of Globomax over the period from date of acquisition to May 31, 2006. Such potential additional consideration will be accounted for as goodwill. The total amount of goodwill is expected to be tax deductible.

The acquisition of Globomax has been accounted for as a purchase in accordance with SFAS No. 141, "Business Combinations". The following table summarises the fair values of the assets acquired and the liabilities assumed at the date of acquisition.

| | At September 9, 2003 (in thousands) |
|-------------------------------|---|
| Property, Plant and Equipment | 352 |
| Goodwill | 13,134 |

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| | |
|----------------------|----------|
| Cash | 891 |
| Other Current Assets | 2,487 |
| Current liabilities | (5,539) |
| ----- | |
| Purchase Price | \$11,325 |
| ----- | |

The results of Globomax have been included in the consolidated financial statements from September 9, 2003.

The proforma effect of the BPA, MCS, Medeval and Globomax acquisitions if completed on June 1, 2002 would have resulted in net revenue, net income and earnings per share for the fiscal years ended May 31, 2003 and 2004 as follows:

| | Year Ended May 31, | |
|----------------------------|---------------------------------------|-----------|
| | 2003 | 2004 |
| | ----- | |
| | (in thousands, except per share data) | |
| Net Revenue | \$254,694 | \$299,948 |
| Net Income | \$20,276 | \$25,918 |
| Basic Earnings per Share | \$1.72 | \$1.95 |
| Diluted Earnings Per Share | \$1.66 | \$1.89 |

In August 2002, prior to the date of acquisition, a U.S.\$900,000 distribution was made by BPA and MCS, to the former shareholders of BPA and MCS, which was recorded as other expenses. In July 2002, distributions were paid to the former shareholders of Medeval by Medeval of Stg(pound)109,700 (U.S.\$168,134) respectively which were also recorded as other expenses. These payments are included in the proforma results above.

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5. Property, Plant and Equipment

| | May 31, | |
|--|----------------|----------|
| | 2003 | 2004 |
| | (in thousands) | |
| Cost | | |
| Land..... | \$717 | \$748 |
| Building..... | 7,874 | 9,502 |
| Computer equipment and software..... | 33,558 | 42,469 |
| Office furniture and fixtures..... | 13,418 | 17,071 |
| Laboratory equipment..... | 3,685 | 5,009 |
| Motor vehicles..... | 38 | 37 |
| Leasehold improvements..... | 6,921 | 6,116 |
| ----- | | |
| | 66,211 | 80,952 |
| Less accumulated depreciation..... | (26,708) | (38,016) |
| ----- | | |
| Property, plant and equipment (net)..... | \$39,503 | \$42,936 |
| ----- | | |

Total cost above at May 31, 2004 includes U.S.\$1,580,127 (2003: U.S.\$524,632) which relates to assets held under capital finance leases. Related accumulated

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depreciation amounted to U.S.\$252,039 (2003: U.S.\$36,272).

6. Other Liabilities

| | 2003 | May 31, 2004 |
|--|----------------|-----------------|
| | (in thousands) | |
| Accrued liabilities..... | \$13,562 | 18,483 |
| Accrued bonuses..... | 8,542 | 8,828 |
| Accrued social welfare costs..... | 1,301 | 1,899 |
| Contingent purchase consideration payable..... | 2,003 | 2,506 |
| Short term government grants..... | 34 | 195 |
| Accrued pension liability (note 8) | 2,632 | 2,927 |
| Short term finance leases (note 14)..... | 215 | 253 |
| | | |
| | \$28,289 | \$35,091 |
| | | |

7. Bank Loans

The Company has short-term bank loan facilities as follows:

On July 3, 2003, ICON entered into a facility agreement (the "Facility Agreement") for the provision of a term loan facility of U.S.\$40 million, multi-currency overdraft facility of \$5 million; and revolving credit facility of \$15 million (the "Facilities") with The Governor and Company of the Bank of Ireland and Ulster Bank Ireland Limited (the "Banks"). The obligations of the borrowers under the Facilities are secured by certain composite guarantees and indemnities and pledges in favour of each of the banks. This facility bears interest at an annual rate equal to the Banks Prime Rate plus three quarters of one percent. As at May 31, 2004, the full amount of these facilities were available to be drawn down. ICON Clinical Research, Inc. (a subsidiary of ICON plc) is entitled to make borrowings under a revolving credit facility of \$15 million. As at May 31, 2004, the full amount of this facility was available to be drawn down.

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The Company entered into an overdraft agreement with Allied Irish Banks, plc ("AIB") whereby the company guarantees any overdraft of the subsidiary ICON Clinical Research GmbH up to an amount (euro)120,000 (U.S.\$146,604). As of May 31, 2004, the full facility was available to be drawn down.

The Company also entered into an overdraft agreement with AIB, whereby the company guaranteed any overdraft of the subsidiary ICON Clinical Research Israel Ltd. up to an amount of U.S.\$250,000. This facility was terminated on April 20, 2004.

On November 17, 1998, the Company entered into an overdraft facility (the "AIB facility") for (euro)2,539,000 (\$3,101,896) with AIB. This facility bore an annual interest rate equal to AIB Bank's Prime Rate plus one-quarter of one percent. The full sum of the unpaid principal and interest was repayable on demand. This facility was terminated on July 3, 2003.

On July 29, 2002, the Company entered into an additional AIB facility for

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Stg(pound)50,000 (\$91,664) This facility bore interest at an annual rate equal to AIB Bank's Prime Rate plus two percent. The full sum of the unpaid principal and interest was repayable on demand. This facility was terminated on July 3, 2003.

Our U.S. subsidiary, ICON Clinical Research, Inc. (the "Borrower"), had a \$12 million secured line of credit (the "PNC Facility") with PNC Bank N.A. ("P.N.C."). The PNC Facility bore interest at an annual rate equal to PNC's Prime Rate less three-quarters of one percent. The full sum of the unpaid principal and interest was payable on demand. The PNC Facility was secured by a first priority security interest in certain assets of the Borrower. This facility was terminated on July 3, 2003.

8. Employee Benefits

Certain Company employees are eligible to participate in a defined contribution plan (the "Plan"). Participants in the Plan may elect to defer a portion of their pre-tax earnings into a pension plan, which is run by an independent party. The Company matches each participant's contributions up to 6% of the participant's annual compensation. Contributions to this plan are recorded, as expense in the Consolidated Statement of Operations. Contributions for the years ended May 31, 2002, 2003 and 2004 were U.S.\$1,265,000, and U.S.\$1,649,793, and U.S.\$2,297,928 respectively.

The Company's United States operations maintain a retirement plan (the "U.S. Plan") that qualifies as a deferred salary arrangement under Section 401(k) of the Internal Revenue Code. Participants in the U.S. Plan may elect to defer a portion of their pre-tax earnings, up to the Internal Revenue Service annual contribution limit. The Company matches 50% of each participant's contributions, each participant can contribute up to 6% of their annual compensation. Contributions to this U.S. Plan are recorded, in the year contributed, as an expense in the Consolidated Statement of Operations. Contributions for the years ended May 31, 2002, 2003 and 2004 were U.S.\$ 1,320,000, U.S.\$ 1,811,156, and U.S.\$2,389,757 respectively.

One of the Company's subsidiaries which was acquired during the 2003 fiscal year, Medeval Group Limited, operates a defined benefit pension plan in the United Kingdom for its employees. The plan is managed externally and the related pension costs and liabilities are assessed in accordance with the advice of a professionally qualified actuary. Plan assets at May 31, 2003 and 2004 consist of units held in independently administered funds. The pension costs of this plan are presented in the following tables in accordance with the requirements of SFAS No.132(R), "Employees' Disclosures about Pensions and Other Post-retirement Benefits".

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| Change in benefit obligation | May 31, 2003 | May 31, 2004 |
|---|----------------|--------------|
| | (in thousands) | |
| Benefit obligation at acquisition date/ beginning of year | \$6,759 | \$7,000 |
| Service cost | 186 | 186 |
| Interest cost | 127 | 127 |

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| | | |
|--|------|----|
| Plan participants' contributions | 96 | |
| Benefits paid | - | (|
| Actuarial loss | (22) | (3 |
| Foreign currency exchange rate changes | 61 | |

| | | |
|-----------------------------------|---------|------|
| Benefit obligation at end of year | \$7,207 | \$9, |
|-----------------------------------|---------|------|

Change in plan assets

May 31, 2003 May 31, 2002
(in thousands)

| | | |
|--|---------|------|
| Fair value of plan assets at acquisition date/ beginning of year | \$4,171 | \$4, |
| Actual return on plan assets | (148) | |
| Employer contributions | 221 | |
| Plan participants' contributions | 96 | |
| Benefits paid | - | (|
| Foreign currency exchange rate changes | 38 | |

| | | |
|--|---------|------|
| Fair value of plan assets at end of year | \$4,378 | \$6, |
|--|---------|------|

Funded status

May 31, 2003 May 31, 2002
(in thousands)

| | | |
|------------------------------|------------|---------|
| Funded status | \$ (2,829) | \$ (2,9 |
| Unrecognized net gain/(loss) | 197 | (1 |

| | | |
|-------------------|------------|---------|
| Pension liability | \$ (2,632) | \$ (3,0 |
|-------------------|------------|---------|

The net periodic pension cost was comprised of the following:

May 31, 2003 May 31, 2002
(in thousands)

| | | |
|--------------------------------|-------|----|
| Service cost | \$186 | \$ |
| Interest cost | 127 | |
| Expected return on plan assets | (99) | (|

| | | |
|----------------------------|-------|----|
| Net periodic pension costs | \$214 | \$ |
|----------------------------|-------|----|

The weighted average assumptions used in the calculation of the pension cost were a discount rate of 5.1% (date of acquisition: 5.25%), an expected return on plan assets of 6.5% (date of acquisition: 6.50%) and a 3.75% (date of acquisition: 3.75%) rate of compensation increase.

The assets of the scheme are invested in a unitised with profits policy. The

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expected long-term rate of return on assets of 6.5% was calculated as the value of the unitised with profits fund after application of a market value reduction factor. The underlying asset split of the fund is shown below.

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| Asset Category | May 31, 2003 | May 31, 2004 |
|----------------|--------------|--------------|
| Equity | 31% | 29% |
| Bonds | 48% | 50% |
| Property | 17% | 18% |
| Cash/ other | 4% | 3% |
| | | |
| | 100.0% | 100.0% |

Weighted average assumptions to determine benefit obligation

| | May 31, 2003 | May 31, 2004 |
|-------------------------------|--------------|--------------|
| Discount rate | 5.25% | 5.1% |
| Rate of compensation increase | 3.75% | 4.5% |

The accumulated benefit obligation for all defined pension plans was \$9.1 million at May 31, 2004 (2003: \$7.2 million). With effect from July 1, 2003, the scheme was closed to new entrants. The company expects to contribute \$0.75 million to its pension fund in fiscal 2005.

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9. Share Options

On January 17, 2003, the Company adopted the Share Option Plan 2003 (the "2003 Plan") pursuant to which the Compensation Committee of the Board may grant options to officers and other employees of the Company or its subsidiaries for the purchase of ordinary shares. Each option will be either an incentive stock option, or ISO, as described in Section 422 of the Code or an employee stock option, or NSO, as described in Section 422 or 423 of the Code. Each grant of an option under the 2003 Plan will be evidenced by a Stock Option Agreement between the optionee and the Company. The exercise price will be specified in each Stock Option Agreement, however option prices for an ISO will not be less than 100% of the fair market value of an ordinary share on the date the option is granted.

An aggregate of 1.5 million ordinary shares have been reserved under the 2003 Plan; and, in no event will the number of ordinary shares that may be issued pursuant to options awarded under the 2003 Plan exceed 10% of the outstanding shares, as defined in the 2003 Plan, at the time of the grant. Further, the maximum number of ordinary shares with respect to which options may be granted under the 2003 Plan during any calendar year to any employee shall be 100,000 ordinary shares.

No options can be granted after January 17, 2013.

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The following table summarizes the transactions for the Company's share option plans for the three year period ended May 31, 2004:

| | Options Granted Prior to Jan 15, 1998 | Options Granted Under Plans |
|-----------------------------|--|--------------------------------|
| Outstanding at May 31, 2001 | 502,660 | 740,760 |
| Granted | - | 223,540 |
| Exercised | (210,630) | (147,470) |
| Canceled | - | (89,240) |
| ----- | ----- | ----- |
| Outstanding at May 31, 2002 | 292,030 | 727,590 |
| ----- | ----- | ----- |
| Granted | - | 283,445 |
| Exercised | - | (39,360) |
| Canceled | - | (78,060) |
| ----- | ----- | ----- |
| Outstanding at May 31, 2003 | 292,030 | 893,615 |
| ----- | ----- | ----- |
| Granted | - | 372,926 |
| Exercised | (244,960) | (251,959) |
| Canceled | - | (68,080) |
| ----- | ----- | ----- |
| Outstanding at May 31, 2004 | 47,070 | 946,502 |
| ----- | ----- | ----- |

None of the share option grants summarized in the above table resulted in compensation expense as the option exercise price was equal to or greater than the estimated fair value of ordinary shares on the date of the grant.

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The following table summarizes information concerning outstanding and exercisable share options as of May 31, 2004:

| Options Outstanding | | | Options Exercisable | |
|----------------------------|---------------------|--|---------------------------------------|--------|
| Range Exercise Price | Number of Shares | Weighted Average Remaining Contractual Life | Weighted Average Exercise Price | Number |
| \$0.07 | 47,070 | 2.5 | \$0.07 | |
| \$15.63 | 7,000 | 4.0 | \$15.63 | |
| \$17.00 | 1,600 | 4.0 | \$17.00 | |
| \$18.00 | 109,240 | 3.0 | \$18.00 | |

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| | | | |
|---------|---------|-----|---------|
| \$21.25 | 70,460 | 5.0 | \$21.25 |
| \$23.80 | 8,000 | 5.0 | \$23.80 |
| \$26.50 | 8,000 | 5.5 | \$26.50 |
| \$27.39 | 4,000 | 4.0 | \$27.39 |
| \$29.00 | 136,760 | 5.6 | \$29.00 |
| \$28.00 | 238,666 | 6.5 | \$28.00 |
| \$42.71 | 1,798 | 7.4 | \$42.71 |
| \$35.50 | 360,978 | 7.7 | \$35.50 |

| | | | |
|----------------|---------|-----|---------|
| \$0.07 - 42.71 | 993,572 | 6.1 | \$27.83 |
|----------------|---------|-----|---------|

Substantially all of the options granted at exercise prices from \$15.63 to \$42.71 vest over a five year period from the date of grant. All other options have fully vested as of May 31, 2004.

The weighted average fair value of stock options granted during fiscal 2002, calculated using the Black-Scholes option pricing model, was \$16.07 using the following assumptions; expected dividend yield - 0%, risk free interest rate - 5.57%, expected volatility - 50% and expected life - 8 years.

The weighted average fair value of stock options granted during fiscal 2003, calculated using the Black-Scholes option pricing model, was \$15.84 using the following assumptions; expected dividend yield - 0%, risk free interest rate - 3.39%, expected volatility - 50% and expected life - 8 years.

The weighted average fair value of stock options granted during fiscal 2004, calculated using the Black-Scholes option pricing model, was \$24.58 using the following assumptions; expected dividend yield - 0%, risk free interest rate - 4.87%, expected volatility - 50% and expected life - 8 years.

Had the Company determined compensation expense based on the fair value at the grant date for these options under SFAS No.123, "Accounting for Stock-Based Compensation", the Company's net income for fiscal 2002, 2003 and 2004 would have been reduced to the pro-forma amounts indicated below.

| | | 2002 | 2003 |
|--|-------------|----------------------------------|----------|
| | | (in thousands, except per share) | |
| Net Income | as reported | \$14,200 | \$18,283 |
| | pro-forma | 12,591 | 16,187 |
| Net Income per ordinary share Basic | as reported | \$1.22 | \$1.55 |
| | pro-forma | 1.08 | 1.37 |
| Diluted | as reported | 1.16 | 1.50 |
| | pro-forma | 1.03 | 1.33 |

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10. Government Grants

| | 2003 | May 31, 2004 |
|---|----------------|-----------------|
| | (in thousands) | |
| Received and receivable | \$1,280 | \$2,225 |
| Less accumulated amortization | (280) | (849) |
| Foreign exchange translation adjustment | 174 | 230 |
| <hr style="border-top: 1px dashed black;"/> | | |
| | 1,174 | 1,606 |
| Less current portion | (34) | (195) |
| <hr style="border-top: 1px dashed black;"/> | | |
| | \$1,140 | \$1,411 |
| <hr style="border-top: 1px dashed black;"/> | | |

Government grants amortized to the profit and loss account amounted to U.S.\$46,000, U.S.\$36,000 and U.S.\$569,000 for the years ended May 31, 2002, 2003 and 2004, respectively.

As of May 31, 2004 the Company had U.S.\$1,351,000 in restricted retained earnings, pursuant to the terms of the grant agreements.

11. Share Capital

Ordinary Shares

Holders of ordinary shares will be entitled to receive such dividends as may be recommended by the board of directors of the Company and approved by the shareholders and/or such interim dividends as the board of directors of the Company may decide. On liquidation or a winding up of the Company, the par value of the ordinary shares will be repaid out of the assets available for distribution among the holders of the Company's ADSs and ordinary shares not otherwise represented by ADRs. Holders of ordinary shares have no conversion or redemption rights. On a show of hands, every holder of an ordinary share present in person at a general meeting of shareholders, and every proxy, shall have one vote, for each ordinary share held with no individual having more than one vote.

On November 22, 2000, the ordinary share capital of the Company was redenominated from IR5p per share to (euro)0.06 per share. The renominization generated a capital conversion reserve fund of (euro)39,499 (U.S.\$47,277) which was recorded within additional paid in capital.

On January 28, 2000, the Company merged with Pacific Research Associates Inc. ("PRAI") in a transaction accounted for as a pooling-of-interests transaction. The Company issued 838,828 ordinary shares of (euro)0.06 each to PRAI shareholders for this transaction. These shares have been treated as outstanding for all periods presented.

On January 27, 2000, the Company acquired YRCR for cash and shares. The Company issued 51,387 ordinary shares of (euro)0.06 each to YRCR shareholders for this transaction. At May 31, 2000, pursuant to an earn-out clause contained in the purchase agreement with YRCR, a further 24,272 ordinary shares of (euro)0.06 each were issued to the YRCR shareholders and on August 31, 2001, a further 10,772 ordinary shares of (euro)0.06 were issued. On October 8, 2002, a further 3,696 ordinary shares of (euro)0.06 were issued (see note 4).

During the year to May 31, 2002, a further 358,100 options were exercised by employees at an average exercise price of U.S.\$7.47 per share.

During the year to May 31, 2003, a further 39,360 options were exercised by employees at an average exercise price of U.S.\$18.51 per share for total

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proceeds of U.S.\$728,554.

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During the year to May 31, 2004, a further 496,919 options were exercised by employees at an average exercise price of U.S.\$10.78 per share for total proceeds of U.S.\$5,357,787.

On August 8, 2003 the Company issued 1,500,000 ordinary shares in a public offering at \$30.47 (net of underwriting discount) per share. The proceeds of this offering were U.S.\$44.3 million (after deducting U.S.\$1.4 million in costs).

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12. Income Taxes

The U.S. based and Irish-based subsidiaries file tax returns in the United States and Ireland, respectively. The other foreign subsidiaries are taxed separately under the laws of their respective countries.

The components of income before provision for income tax expense are as follows:

| | 2002 | Year Ended May 31, 2003 (in thousand) |
|---|----------|---|
| Ireland | \$7,702 | \$6,556 |
| Other | 11,627 | 18,727 |
| <hr style="border-top: 1px dashed black;"/> | | |
| Income before provision for income taxes | \$19,329 | \$25,283 |
| <hr style="border-top: 1px dashed black;"/> | | |

The components of total income tax expense are as follows:

| | 2002 | Year Ended May 31, 2003 (in thousand) |
|---|---------|---|
| Provision for income taxes | | |
| Current: | | |
| Ireland | \$1,164 | \$1,158 |
| United States | 3,684 | 4,334 |
| Other | 262 | 1,132 |
| <hr style="border-top: 1px dashed black;"/> | | |
| | 5,110 | 6,624 |

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| | | |
|---|---------|---------|
| Deferred expenses/(benefit): | | |
| Ireland | - | 31 |
| United States | 19 | 345 |
| ----- | | |
| Provision for income taxes | 5,129 | 7,000 |
| Shareholders' equity for compensation expense for tax purposes in excess of amounts recognized for financial reporting purposes | (792) | (48) |
| ----- | | |
| Total | \$4,337 | \$6,952 |
| ----- | | |

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On January 1, 2001, Ireland's statutory income tax rate decreased from 24% to 20%, on January 1, 2002 from 20% to 16% and on January 1, 2003, from 16% to 12.5%. Certain activities carried out by the Irish company, principally data processing services, are taxed at a reduced rate of 10%. The Company's consolidated effective tax rate differed from the blended statutory rate as set forth below;

| | 2002 | Year Ended May 31, 2003 (in thousand) |
|--|---------|---|
| Taxes at Irish statutory rate of 12.50% (14.54% in 2003; 18.33% in 2002) | \$3,543 | \$3,676 |
| Foreign and other income taxed at higher/(reduced) rates | 589 | 1,874 |
| United States state tax net of United States Federal benefit | 468 | 556 |
| Movement in valuation allowance | (127) | 374 |
| Current year under-provision in respect of foreign taxes | - | - |
| Reversal of prior year over-provision in respect of foreign taxes | - | - |
| Non deductible expenses | 161 | 35 |
| Other | 495 | 485 |
| ----- | | |
| Total provision for income taxes | \$5,129 | \$7,000 |
| ----- | | |

The tax effects of temporary differences that give rise to significant portions of deferred tax assets and deferred tax liabilities are presented below:

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| | Year Ended May 31, | |
|---|--------------------|---------|
| | 2003 | 2004 |
| | (in thousands) | |
| Deferred tax liabilities: | | |
| Property, plant and equipment | \$764 | \$2,180 |
| Goodwill and related assets | 828 | 1,023 |
| Other | 172 | - |
| ----- | | |
| Total deferred tax liabilities | 1,764 | 3,203 |
| Deferred tax assets: | | |
| Net operating loss carryforwards | 2,292 | 3,880 |
| Accrued expenses and payments on account | 946 | 1,565 |
| Deferred compensation expense | 474 | 166 |
| ----- | | |
| Total deferred tax assets | 3,712 | 5,611 |
| Valuation allowance for deferred tax assets | (1,916) | (3,361) |
| ----- | | |
| Deferred tax assets recognized | \$1,796 | \$2,250 |
| ----- | | |
| Net deferred tax asset / (liability) | \$32 | \$(953) |
| ----- | | |

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U.S.\$566,000 of the deferred tax asset of U.S.\$2,250,000 above is non-current. This amount has been offset against the deferred tax liabilities of U.S.\$3,203,000 above (all of which are non-current) resulting in a net non-current deferred tax liability of U.S.\$2,637,000 and a net current deferred tax asset of U.S.\$1,684,000.

At May 31, 2004, European subsidiaries had operating loss carryforwards for income tax purposes that may be carried forward indefinitely, available to offset against future taxable income, if any, of approximately U.S.\$5.0 million

At May 31, 2004, a U.S. subsidiary had a net operating loss carryforwards for U.S. Federal and State income tax purposes, available to offset against future taxable income if any of approximately U.S.\$5.8 million for U.S. Federal and U.S.\$7.2 million for State income tax, which expire between 2009 and 2024.

Of the U.S.\$5.8 million U.S. Federal and U.S.\$7.2 million State net operating losses, approximately U.S.\$4.0 million and U.S.\$5.7 million respectively will be available for offset against future taxable income, if any, of future accounting periods. The subsidiary's ability to use the remaining net operating loss carryforward of U.S.\$1.8 million for Federal and U.S.\$1.5 million for State taxes is limited to U.S.\$113,000 per year due to the subsidiary experiencing a change of ownership in 2000, as defined by Section 382 of the Internal Revenue Code of 1986, as amended.

A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company has provided a valuation allowance for the years ended May 31, 2004 and 2003 of

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U.S.\$3,361,000 and U.S.\$1,916,000 respectively. This valuation allowance is based on management's belief that it is more likely than not that the European and US entities' losses and other deferred tax assets will not be utilized given their history of operating losses. The valuation allowance was U.S.\$1.8 million as of June 1, 2001 and decreased by U.S.\$184,000 for year ended May 31, 2002 and increased by U.S.\$298,000 and U.S.\$1.4 million for the years ended 31 May 2003 and 2004 respectively.

Subsequent recognized tax benefits relating to the valuation allowance for deferred tax assets in the amount of U.S.\$800,000 as of May 31, 2004 will be allocated to goodwill and other non-current intangible assets.

13. Significant Concentrations

The Company does business with most major international pharmaceutical companies (see note 15). The Company provided \$355,000 during the year ended May 31, 2004 for doubtful debts.

14. Commitments and Contingencies

The Company is not party to any litigation or other legal proceedings that the Company believes could reasonably be expected to have a material adverse effect on the Company's business, results of operations and financial condition.

The Company has several non-cancelable operating leases, primarily for facilities, that expire over the next 10 years. These leases generally contain renewal options and require the Company to pay all executory costs such as maintenance and insurance. The Company paid U.S.\$10,963,000, U.S.\$15,743,000 and U.S.\$22,179,000 in rental expense for the fiscal years ended May 31, 2002, 2003 and 2004, respectively. Future minimum rental commitments for operating leases with non-cancelable terms in excess of one year are as follows:

| | Minimum rental payments (in thousands) |
|------------|---|
| 2005 | \$21,845 |
| 2006 | 19,049 |
| 2007 | 14,698 |
| 2008 | 13,364 |
| 2009 | 12,949 |
| Thereafter | \$65,998 |
| | |

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The Company has a number of finance leases, primarily over furniture and equipment, that expire over the next four years. Future commitments are as follows:

| | Lease payments (in thousands) |
|-----------------------------|----------------------------------|
| 2005 | \$310 |
| 2006 | 109 |
| 2007 | 64 |
| 2008 | 27 |
| Thereafter | 3 |
| Less future finance charges | (94) |

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The Company made a number of acquisitions in recent years with earn-out provisions built into the purchase contracts, which may require cash payments of U.S.\$2,506,000 to be made during fiscal 2005.

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15. Business Segment Information

The Company operates predominantly in the contract clinical research industry providing a broad range of clinical research and integrated product development services on a global basis for the pharmaceutical and biotechnology industries. On June 8, 2000, the Company acquired for cash UCT (U.S.), Inc. ("UCT"), subsequently renamed ICON Laboratories Inc., a central laboratory company based in New York, USA. This, together with laboratory services based in Dublin, form the central laboratory information disclosed below.

The Company's areas of operation outside of Ireland principally include the United Kingdom, United States, Germany, Australia, Argentina, France, Japan, Israel, Singapore, Canada, Sweden, The Netherlands, Latvia, South Africa and India. Segment information for the fiscal years ended May 31, 2002, 2003 and 2004 is as follows:

a) The distribution of net revenue by geographical area was as follows:

| | Year Ended May 31, | | |
|----------------|--------------------|-----------|-----------|
| | 2002 | 2003 | 2004 |
| | (in thousands) | | |
| Ireland* | \$20,406 | \$26,293 | \$35,109 |
| Rest of Europe | 24,605 | 34,727 | 65,930 |
| U.S. | 107,520 | 158,707 | 185,301 |
| Other | 4,024 | 5,998 | 10,583 |
| | | | |
| Total | \$156,555 | \$225,725 | \$296,923 |
| | | | |

* All sales shown for Ireland are export sales.

b) The distribution of net revenue by business segment was as follows:

| | Year Ended May 31, | | |
|--------------------|--------------------|-----------|-----------|
| | 2002 | 2003 | 2004 |
| | (in thousands) | | |
| Central laboratory | \$25,887 | \$26,168 | \$26,905 |
| Clinical research | 130,668 | 199,557 | 270,018 |
| | | | |
| Total | \$156,555 | \$225,725 | \$296,923 |
| | | | |

c) The distribution of income from operations by geographical area was as follows:

| | Year Ended May 31, | | |
|---------|--------------------|---------|---------|
| | 2002 | 2003 | 2004 |
| | (in thousands) | | |
| Ireland | \$7,706 | \$6,532 | \$9,363 |

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| | | | |
|----------------|----------|----------|----------|
| Rest of Europe | (3,397) | 1,192 | 10,209 |
| U.S. | 13,398 | 17,091 | 13,023 |
| Other | 506 | 114 | 1,788 |
| ----- | | | |
| Total | \$18,213 | \$24,929 | \$34,383 |
| ----- | | | |

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- d) The distribution of income from operations by business segment was as follows:

| | | | |
|--------------------|----------|--------------------|-----------|
| | | Year Ended May 31, | |
| | 2002 | 2003 | 2004 |
| | | (in thousands) | |
| Central laboratory | \$3,660 | \$115 | (\$3,274) |
| Clinical research | 14,553 | 24,814 | 37,657 |
| ----- | | | |
| Total | \$18,213 | \$24,929 | \$34,383 |
| ----- | | | |

- e) The distribution of property, plant and equipment, net, by geographical area was as follows:

| | | | |
|----------------|----------|--------------------|--|
| | | Year Ended May 31, | |
| | 2003 | 2004 | |
| | | (in thousands) | |
| Ireland | \$17,003 | \$18,799 | |
| Rest of Europe | 6,316 | 7,202 | |
| U.S. | 15,066 | 15,935 | |
| Other | 1,118 | 1,000 | |
| ----- | | | |
| Total | \$39,503 | \$42,936 | |
| ----- | | | |

- f) The distribution of property, plant and equipment, net, by business segment was as follows:

| | | | |
|--------------------|----------|--------------------|--|
| | | Year Ended May 31, | |
| | 2003 | 2004 | |
| | | (in thousands) | |
| Central laboratory | \$3,560 | \$3,989 | |
| Clinical research | 35,943 | 38,947 | |
| ----- | | | |
| Total | \$39,503 | \$42,936 | |
| ----- | | | |

- g) The distribution of depreciation by geographical area was as follows:

| | | | |
|--|--------------------|------|------|
| | Year Ended May 31, | | |
| | 2002 | 2003 | 2004 |

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| | (in thousands) | | |
|----------------|----------------|---------|----------|
| Ireland | \$1,302 | \$2,330 | \$3,710 |
| Rest of Europe | 975 | 1,138 | 1,842 |
| U.S. | 3,513 | 3,535 | 5,271 |
| Other | 230 | 302 | 348 |
| ----- | | | |
| Total | \$6,020 | \$7,305 | \$11,171 |
| ----- | | | |

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h) The distribution of depreciation by business segment was as follows:

| | 2002 | Year Ended May 31, 2003 | 2004 |
|--------------------|----------------|----------------------------|----------|
| | (in thousands) | | |
| Central laboratory | \$591 | \$732 | \$1,014 |
| Clinical research | 5,429 | 6,573 | 10,157 |
| ----- | | | |
| Total | \$6,020 | \$7,305 | \$11,171 |
| ----- | | | |

i) The distribution of total assets by geographical area was as follows:

| | 2003 | Year Ended May 31, 2004 |
|----------------|----------------|----------------------------|
| | (in thousands) | |
| Ireland | \$59,838 | \$76,165 |
| Rest of Europe | 60,982 | 115,056 |
| U.S. | 110,602 | 141,104 |
| Other | 3,592 | 2,998 |
| ----- | | |
| Total | \$235,014 | \$335,323 |
| ----- | | |

j) The distribution of total assets by business segment was as follows:

| | 2003 | Year Ended May 31, 2004 |
|--------------------|----------------|----------------------------|
| | (in thousands) | |
| Central laboratory | \$19,175 | \$20,343 |
| Clinical research | 215,839 | 314,980 |
| ----- | | |
| Total | \$235,014 | \$335,323 |
| ----- | | |

k) The distribution of capital expenditures by geographical area was as follows:

Year Ended May 31,

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| | 2002 | 2003 (in thousands) | 2004 |
|----------------|----------|------------------------|----------|
| Ireland | \$3,158 | \$6,375 | \$4,812 |
| Rest of Europe | 2,563 | 1,686 | 2,167 |
| U.S. | 4,938 | 7,274 | 5,826 |
| Other | 291 | 658 | 160 |
| ----- | | | |
| Total | \$10,950 | \$15,993 | \$12,965 |
| ----- | | | |

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- 1) The distribution of capital expenditures by business segment was as follows:

| | 2002 | Year Ended May 31, 2003 (in thousands) | 2004 |
|--------------------|----------|--|----------|
| Central laboratory | \$1,965 | \$1,520 | \$1,552 |
| Clinical research | 8,985 | 14,473 | 11,413 |
| ----- | | | |
| Total | \$10,950 | \$15,993 | \$12,965 |
| ----- | | | |

- m) The following table sets forth the clients which represented 10% or more of the Company's net revenue in each of the periods set out below.

| | 2002 | Year Ended May 31, 2003 | 2004 |
|----------|------|----------------------------|------|
| Client A | 14% | 10% | * |
| Client B | 16% | 21% | 17% |
| Client C | 13% | * | * |
| Client D | * | 11% | * |

* Net Revenue did not exceed 10%

16. Supplemental Disclosure of Cash Flow Information

| | 2002 | Year Ended May 31, 2003 (in thousands) | 2004 |
|----------------------------|---------|--|---------|
| Cash paid for interest | \$462 | \$279 | \$202 |
| ----- | | | |
| Cash paid for income taxes | \$2,514 | \$7,186 | \$5,731 |
| ----- | | | |

17. New Accounting Pronouncements

In December 2003, the FASB issued Interpretation No. 46, revised--Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51 ("FIN 46R"). FIN

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46R addresses the consolidation of variable interest entities ("VIEs"), which include entities that have one or more of the following characteristics: (1) The equity investment at risk is not sufficient to permit the entity to finance its activities without additional subordinated financial support; (2) The equity investors lack essential characteristics of a controlling financial interest (as defined by FIN 46R); and (3) The equity investors have voting rights that are not proportionate to their economic interests, and the activities of the entity involve or are conducted on behalf of an investor with a disproportionately small voting interest. In addition, FIN 46R provides for certain scope exceptions to its application. Adoption of this Interpretation is required in financial statements that have interests in VIEs or potential VIEs, commonly referred to as special-purpose entities, for periods ending after 15 December 2003. Application for all other types of entities is required in financial statements for periods ending after 15 March 2004. The adoption of FIN 46R has not had a material impact on the Company's Consolidated Financial Statements.

On April 30, 2003, the FASB issued FASB Statement No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities, which amends FASB Statement No. 133, Accounting for Derivative Instruments and Hedging Activities, to address (1) decisions reached by the Derivatives Implementation Group, (2) developments in other Board projects that address financial instruments, and (3) implementation issues related to the definition of a derivative. Statement 149 has

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multiple effective date provisions depending on the nature of the amendment to Statement 133. Under SFAS No. 133, the Company's foreign exchange contracts do not qualify for hedge accounting treatment. The impact of adopting Statement 149 did not have a significant impact on our financial statements.

On May 15, 2003, the FASB issued FASB Statement No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity". This Statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003, except for certain mandatorily redeemable financial instruments. It is to be implemented by reporting the cumulative effect of a change in an accounting principle for financial instruments created before the issuance date of the Statement and still existing at the beginning of the interim period of adoption. Restatement is not permitted. The adoption of SFAS No.150 did not have a significant impact on our financial statements.

The Emerging Issues Task Force (EITF) has reached a final consensus on EITF Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. This Issue addresses certain aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities, specifically how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting. The Issue also addresses how arrangement consideration should be measured and allocated to the separate units of accounting in the arrangement. The guidance in this Issue is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003, with a possible alternative means of adoption by applying the new rules to existing contracts and recording the effect of adoption as a cumulative effect of a change in accounting principle. Early adoption is permitted. We adopted EITF Issue No. 00-21 on June 1, 2003. The adoptions of EITF Issue No. 00-21 did

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not have a significant impact on our financial statements.

18. Related Parties

On February 6, 1998, ICON entered into an Option Agreement ("The Put Option") with Rosa Investment Limited ("Rosa"). Rosa's sole activity was to hold an investment in Clear Investments Limited ("Clear"), the sole activity of which was to hold Mr. Gray's option to exercise 54,000 ordinary shares. Mr. Gray is a director of Rosa and Clear. Rosa is owned by a trust of which Mr. Gray is a beneficiary. On the April 21, 2004, Mr. Gray subsequently acquired Clear from Rosa and exercised the Put Option in accordance with the terms of the Option Agreement. On April 22, 2004, pursuant to the Option Agreement, ICON purchased the outstanding share capital in Clear from Mr. Gray, the consideration for the acquisition being the issuance of 54,000 fully paid up ordinary shares in ICON, to Mr. Gray, such a sale being the economic equivalent of Mr. Gray exercising his stock options.

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the Registrant certifies that it meets all of the requirements for filing on Form 20-F and has duly caused this annual report to be signed on its behalf by the undersigned thereunto duly authorized.

ICON public limited company

July 23, 2004

Date

/s/ Sean Leech

Sean Leech
Chief Financial Officer

Certification of Chief Executive Officer
Pursuant to Section 302 of
the Sarbanes-Oxley Act of 2002

I, Peter Gray, certify that:

- 1. I have reviewed this annual report on Form 20-F of ICON plc ("the registrant").
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

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3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 30, 2004

/s/ Peter Gray

Peter Gray
Chief Executive Officer

Certification of Chief Financial Officer
Pursuant to Section 302 of
the Sarbanes-Oxley Act of 2002

I, Sean Leech, certify that:

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1. I have reviewed this annual report on Form 20-F of ICON plc ("the registrant").
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 30, 2004

/s/ Sean Leech

Sean Leech
Chief Financial Officer

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As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of ICON plc (the "Company") on Form 20-F for the period ending May 31, 2003, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Peter Gray, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 30, 2004

/s/ Peter Gray

Peter Gray
Chief Executive Officer

The foregoing certification is being furnished solely pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code) and is not being filed as part of the report or as a separate disclosure document. A signed original of this written statement required by section 906 has been provided to ICON plc and will be retained by ICON plc and furnished to the Securities and Exchange Commission or its staff upon request.

Certification Pursuant to 18 U.S.C. Section 1350,
As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of ICON plc (the "Company") on Form 20-F for the period ending May 31, 2003, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Sean Leech, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 30, 2004

/s/ Sean Leech

Sean Leech
Chief Financial Officer

The foregoing certification is being furnished solely pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code) and is not being filed as part of the report or as a separate disclosure document. A signed original of this written statement required by section 906 has been provided to ICON plc and will be retained by ICON plc and furnished to the Securities and Exchange Commission or its staff upon request.

